

**Clinical trial results:****A Phase 1/2, Open-label, Multi-center Study to Assess the Safety and Tolerability of Durvalumab (Anti-PD-L1 Antibody) as Monotherapy and in Combination Therapy in Subjects With Lymphoma or Chronic Lymphocytic Leukemia****Summary**

EudraCT number	2015-003516-21
Trial protocol	GB DE NL IT
Global end of trial date	21 August 2022

**Results information**

Result version number	v2 (current)
This version publication date	25 October 2023
First version publication date	06 September 2023
Version creation reason	

**Trial information****Trial identification**

Sponsor protocol code	MEDI4736-NHL-001
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**Additional study identifiers**

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02733042
WHO universal trial number (UTN)	-

Notes:

**Sponsors**

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

Notes:

**Paediatric regulatory details**

Is trial part of an agreed paediatric investigation plan (PIP)	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	20 August 2022
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	21 August 2022
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

To assess the safety and tolerability of durvalumab when given in combination with lenalidomide and rituximab; ibrutinib; or bendamustine and rituximab in participants with lymphoma or chronic lymphocytic leukemia.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 May 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	France: 22
Country: Number of subjects enrolled	Italy: 23
Country: Number of subjects enrolled	Japan: 12
Country: Number of subjects enrolled	United Kingdom: 18
Country: Number of subjects enrolled	United States: 25
Country: Number of subjects enrolled	Netherlands: 6
Worldwide total number of subjects	106
EEA total number of subjects	51

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)	44
From 65 to 84 years	62
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

106 participants were treated.

### Period 1

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

### Arms

Are arms mutually exclusive?	Yes
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<b>Arm title</b>	Part 1 Arm A: DUR 1500 + LEN 20
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Arm description:

Participants received durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13 (ie, 12 months) and lenalidomide (LEN) 20 mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for participants with indolent non-Hodgkin's lymphoma (NHL) or for all cycles of treatment period until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL.

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

Dosage and administration details:

Lenalidomide (LEN) 20 mg orally once daily on Days 1 to 21 of Cycles 1 through 13

Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

<b>Arm title</b>	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375
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Arm description:

Durvalumab (DUR) 1500mg IV infusion on Day 1 of Cycles 1 to 13 and lenalidomide (LEN) 20mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for subjects with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and rituximab (RIT) 375 mg/m<sup>2</sup> IV infusion on Days 2, 8, 15, and 22 of Cycle 1 and on Day 1 of every 28-day cycle from Cycles 2 through 5.

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Rituximab (RIT) 375 mg/m<sup>2</sup> IV infusion on Days 2, 8, 15, and 22 of Cycle 1 and on Day 1 of every 28-day cycle from Cycles 2 through 5

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

Dosage and administration details:

Lenalidomide (LEN) 20 mg orally once daily on Days 1 to 21 of Cycles 1 through 13

<b>Arm title</b>	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375
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Arm description:

Participants received durvalumab (DUR) 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and lenalidomide (LEN) 10 mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for participants with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and rituximab 375 mg/m<sup>2</sup> IV infusion on Days 2, 8, 15, 22 of Cycle 1 and on Day 1 of every 28-day cycle from Cycles 2 through 5.

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Rituximab (RIT) 375 mg/m<sup>2</sup> IV infusion on Days 2, 8, 15, and 22 of Cycle 1 and on Day 1 of every 28-day cycle from Cycles 2 through 5

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

Dosage and administration details:

Lenalidomide (LEN) 10 mg orally once daily on Days 1 to 21 of Cycles 1 through 13

<b>Arm title</b>	Part 1 Arm B: DUR 1500 + IBR 420
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Arm description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib (IBR) 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Arm type	Experimental
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Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13	
Investigational medicinal product name	Ibrutinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
Ibrutinib (IBR) 420 mg orally once daily	
<b>Arm title</b>	Part 1 Arm B: DUR 1500 + IBR 560
Arm description:	
Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 560 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.	
Arm type	Experimental
Investigational medicinal product name	Ibrutinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
Ibrutinib (IBR) 560 mg orally once daily	
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13	
<b>Arm title</b>	Part 1 Arm C: DUR 1500 + RIT 375
Arm description:	
Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, and rituximab 375 mg/m <sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6 (for participants with CLL the rituximab dose was 375 mg/m <sup>2</sup> Cycle 1 first dose and 500 mg/m <sup>2</sup> for each subsequent dose).	
Arm type	Experimental
Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Rituximab 375 mg/m <sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6 (for participants with CLL the rituximab dose was 375 mg/m <sup>2</sup> Cycle 1 first dose and 500 mg/m <sup>2</sup> for each subsequent dose).	
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

<b>Arm title</b>	Part 1 Arm C: DUR 1500 + BEN 70
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Arm description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and bendamustine (BEN) 70 mg/m<sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6.

Arm type	Experimental
Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravesical use

Dosage and administration details:

Bendamustine (BEN) 70 mg/m<sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6.

Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

<b>Arm title</b>	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70
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Arm description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m<sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m<sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m<sup>2</sup> Cycle 1 first dose and 500 mg/m<sup>2</sup> for each subsequent dose).

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravesical use

Dosage and administration details:

Bendamustine (BEN) 70 mg/m<sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6.

Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Rituximab 375 mg/m<sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6 (for participants with CLL the

rituximab dose was 375 mg/m<sup>2</sup> Cycle 1 first dose and 500 mg/m<sup>2</sup> for each subsequent dose).

<b>Arm title</b>	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90
Arm description: Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 90 mg/m <sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m <sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m <sup>2</sup> Cycle 1 first dose and 500 mg/m <sup>2</sup> for each subsequent dose).	
Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13	
Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravesical use
Dosage and administration details: Bendamustine (BEN) 90 mg/m <sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6.	
Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Rituximab 375 mg/m <sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6 (for participants with CLL the rituximab dose was 375 mg/m <sup>2</sup> Cycle 1 first dose and 500 mg/m <sup>2</sup> for each subsequent dose).	
<b>Arm title</b>	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420
Arm description: Participants with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.	
Arm type	Experimental
Investigational medicinal product name	Ibrutinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: Ibrutinib (IBR) 420 mg orally once daily	
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

<b>Arm title</b>	Part 2 Arm B MCL: DUR 1500 + IBR 560
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Arm description:

Participants with mantle cell lymphoma (MCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 560 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

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

Dosage and administration details:

Ibrutinib (IBR) 560 mg orally once daily

Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

<b>Arm title</b>	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70
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Arm description:

Participants with follicular lymphoma (FL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m<sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m<sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6.

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Bendamustine (BEN) 70 mg/m<sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6.

Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Rituximab 375 mg/m<sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6

<b>Arm title</b>	Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70
Arm description:	
Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m <sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m <sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6.	
Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13	
Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravesical use
Dosage and administration details:	
Bendamustine (BEN) 70 mg/m <sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6.	
Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Rituximab 375 mg/m <sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6	
<b>Arm title</b>	Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70
Arm description:	
Participants with CLL or SLL received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m <sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m <sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m <sup>2</sup> Cycle 1 first dose and 500 mg/m <sup>2</sup> for each subsequent dose).	
Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13	
Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Rituximab 375 mg/m <sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6 (for participants with CLL the rituximab dose was 375 mg/m <sup>2</sup> Cycle 1 first dose and 500 mg/m <sup>2</sup> for each subsequent dose).	
Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion

Routes of administration	Intravesical use
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Dosage and administration details:

Bendamustine (BEN) 70 mg/m<sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6.

<b>Arm title</b>	Part 2 Arm D FL: DUR 1500
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Arm description:

Participants with follicular lymphoma received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

<b>Arm title</b>	Part 2 Arm D DLBCL: DUR 1500
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Arm description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

<b>Arm title</b>	Part 2 Arm D CLL/SLL: DUR 1500
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Arm description:

Participants with CLL or SLL received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

<b>Arm title</b>	Part 2 Arm D MCL: DUR 1500
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Arm description:

Participants with mantle cell lymphoma (MCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

<b>Arm title</b>	Part 2 Arm D HL: DUR 1500
Arm description: Participants with Hodgkin lymphoma (HL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.	
Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

Number of subjects in period 1	Part 1 Arm A: DUR 1500 + LEN 20	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375
	Started	3	3
Entered follow-up	3	3	6
Completed	0	1	1
Not completed	3	2	7
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	1	2
Adverse event, non-fatal	1	-	1
Other Reasons	-	-	1
Progressive Disease	2	1	3

Number of subjects in period 1	Part 1 Arm B: DUR 1500 + IBR 420	Part 1 Arm B: DUR 1500 + IBR 560	Part 1 Arm C: DUR 1500 + RIT 375
	Started	3	4
Entered follow-up	3	2	2
Completed	0	1	0
Not completed	3	3	3
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	1	1	-
Adverse event, non-fatal	1	-	-
Other Reasons	-	-	-
Progressive Disease	1	2	3

Number of subjects in period 1	Part 1 Arm C: DUR 1500 + BEN 70	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90

Started	1	4	5
Entered follow-up	0	4	4
Completed	0	1	0
Not completed	1	3	5
Adverse event, serious fatal	1	-	1
Consent withdrawn by subject	-	-	1
Adverse event, non-fatal	-	-	-
Other Reasons	-	-	-
Progressive Disease	-	3	3

<b>Number of subjects in period 1</b>	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420	Part 2 Arm B MCL: DUR 1500 + IBR 560	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70
Started	10	10	10
Entered follow-up	4 <sup>[1]</sup>	5	9
Completed	6	4	4
Not completed	4	6	6
Adverse event, serious fatal	-	1	-
Consent withdrawn by subject	1	-	2
Adverse event, non-fatal	-	2	2
Other Reasons	1	1	-
Progressive Disease	2	2	2

<b>Number of subjects in period 1</b>	Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70	Part 2 Arm C CLL/SLL: DUR 1500 +RIT 375 +BEN 70	Part 2 Arm D FL: DUR 1500
Started	10	5	5
Entered follow-up	9	4	1
Completed	1	1	0
Not completed	9	4	5
Adverse event, serious fatal	-	-	1
Consent withdrawn by subject	1	1	-
Adverse event, non-fatal	-	2	-
Other Reasons	-	-	-
Progressive Disease	8	1	4

<b>Number of subjects in period 1</b>	Part 2 Arm D DLBCL: DUR 1500	Part 2 Arm D CLL/SLL: DUR 1500	Part 2 Arm D MCL: DUR 1500
Started	10	2	5
Entered follow-up	5	0	3
Completed	0	0	0
Not completed	10	2	5
Adverse event, serious fatal	2	-	-
Consent withdrawn by subject	-	-	-
Adverse event, non-fatal	-	-	1
Other Reasons	1	-	1

Progressive Disease	7	2	3
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<b>Number of subjects in period 1</b>	Part 2 Arm D HL: DUR 1500
Started	5
Entered follow-up	2
Completed	1
Not completed	4
Adverse event, serious fatal	-
Consent withdrawn by subject	-
Adverse event, non-fatal	-
Other Reasons	-
Progressive Disease	4

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Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: 106 participants were treated. 69 participants entered follow-up period after completing or discontinuing study treatment.

## Baseline characteristics

### Reporting groups

Reporting group title	Part 1 Arm A: DUR 1500 + LEN 20
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Reporting group description:

Participants received durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13 (ie, 12 months) and lenalidomide (LEN) 20 mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for participants with indolent non-Hodgkin's lymphoma (NHL) or for all cycles of treatment period until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL.

Reporting group title	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375
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Reporting group description:

Durvalumab (DUR) 1500mg IV infusion on Day 1 of Cycles 1 to 13 and lenalidomide (LEN) 20mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for subjects with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and rituximab (RIT) 375 mg/m<sup>2</sup> IV infusion on Days 2, 8, 15, and 22 of Cycle 1 and on Day 1 of every 28-day cycle from Cycles 2 through 5.

Reporting group title	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375
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Reporting group description:

Participants received durvalumab (DUR) 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and lenalidomide (LEN) 10 mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for participants with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and rituximab 375 mg/m<sup>2</sup> IV infusion on Days 2, 8, 15, 22 of Cycle 1 and on Day 1 of every 28-day cycle from Cycles 2 through 5.

Reporting group title	Part 1 Arm B: DUR 1500 + IBR 420
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Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib (IBR) 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Reporting group title	Part 1 Arm B: DUR 1500 + IBR 560
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Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 560 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Reporting group title	Part 1 Arm C: DUR 1500 + RIT 375
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Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, and rituximab 375 mg/m<sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6 (for participants with CLL the rituximab dose was 375 mg/m<sup>2</sup> Cycle 1 first dose and 500 mg/m<sup>2</sup> for each subsequent dose).

Reporting group title	Part 1 Arm C: DUR 1500 + BEN 70
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Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and bendamustine (BEN) 70 mg/m<sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6.

Reporting group title	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70
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Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m<sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m<sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m<sup>2</sup> Cycle 1 first dose and 500 mg/m<sup>2</sup> for each subsequent dose).

Reporting group title	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90
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Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 90 mg/m<sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m<sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m<sup>2</sup> Cycle 1 first dose and 500 mg/m<sup>2</sup> for each subsequent dose).

Reporting group title	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420
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Reporting group description:

Participants with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) received

durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Reporting group title	Part 2 Arm B MCL: DUR 1500 + IBR 560
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Reporting group description:

Participants with mantle cell lymphoma (MCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 560 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Reporting group title	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70
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Reporting group description:

Participants with follicular lymphoma (FL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m<sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m<sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6.

Reporting group title	Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70
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Reporting group description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m<sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m<sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6.

Reporting group title	Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70
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Reporting group description:

Participants with CLL or SLL received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m<sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m<sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m<sup>2</sup> Cycle 1 first dose and 500 mg/m<sup>2</sup> for each subsequent dose).

Reporting group title	Part 2 Arm D FL: DUR 1500
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Reporting group description:

Participants with follicular lymphoma received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

Reporting group title	Part 2 Arm D DLBCL: DUR 1500
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Reporting group description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

Reporting group title	Part 2 Arm D CLL/SLL: DUR 1500
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Reporting group description:

Participants with CLL or SLL received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

Reporting group title	Part 2 Arm D MCL: DUR 1500
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Reporting group description:

Participants with mantle cell lymphoma (MCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

Reporting group title	Part 2 Arm D HL: DUR 1500
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Reporting group description:

Participants with Hodgkin lymphoma (HL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

Reporting group values	Part 1 Arm A: DUR 1500 + LEN 20	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375
Number of subjects	3	3	8
Age Categorical Units: participants			
< 65 Years	1	1	2
≥ 65 Years	2	2	6
Age Continuous Units: years			
median	71.0	66.0	77.0
full range (min-max)	50 to 78	52 to 75	53 to 80

Sex: Female, Male Units: participants			
Female	1	0	2
Male	2	3	6
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	2	2	7
Unknown or Not Reported	1	1	1
Race/Ethnicity, Customized Units: Subjects			
White	2	2	3
Asian	0	0	3
Black or African American	0	0	0
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Other	0	0	1
Not Collected or Reported	1	1	1
Histology Units: Subjects			
Follicular lymphoma	1	3	1
Diffuse large B-cell lymphoma	2	0	4
Marginal zone lymphoma	0	0	2
Transformed follicular lymphoma	0	0	1
Mantle cell lymphoma	0	0	0
CLL / SLL	0	0	0
Hodgkin lymphoma	0	0	0
Eastern Cooperative Oncology Group (ECOG) Performance Status			
ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead			
Units: Subjects			
0 - Fully Active	0	2	2
1 - Restricted but ambulatory	3	1	4
2 - Ambulatory but unable to work	0	0	2
3 - Limited self-care	0	0	0

<b>Reporting group values</b>	Part 1 Arm B: DUR 1500 + IBR 420	Part 1 Arm B: DUR 1500 + IBR 560	Part 1 Arm C: DUR 1500 + RIT 375
Number of subjects	3	4	3
Age Categorical Units: participants			
< 65 Years	2	1	0
≥ 65 Years	1	3	3
Age Continuous Units: years			
median	58.0	68.0	79.0
full range (min-max)	54 to 74	57 to 81	76 to 80

Sex: Female, Male			
Units: participants			
Female	0	2	2
Male	3	2	1
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	2	3	1
Unknown or Not Reported	1	0	2
Race/Ethnicity, Customized			
Units: Subjects			
White	2	4	0
Asian	0	0	0
Black or African American	0	0	0
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Other	0	0	0
Not Collected or Reported	1	0	3
Histology			
Units: Subjects			
Follicular lymphoma	1	0	1
Diffuse large B-cell lymphoma	0	0	2
Marginal zone lymphoma	0	3	0
Transformed follicular lymphoma	0	0	0
Mantle cell lymphoma	1	1	0
CLL / SLL	1	0	0
Hodgkin lymphoma	0	0	0
Eastern Cooperative Oncology Group (ECOG) Performance Status			
ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead			
Units: Subjects			
0 - Fully Active	0	1	1
1 - Restricted but ambulatory	3	3	2
2 - Ambulatory but unable to work	0	0	0
3 - Limited self-care	0	0	0

<b>Reporting group values</b>	Part 1 Arm C: DUR 1500 + BEN 70	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90
Number of subjects	1	4	5
Age Categorical			
Units: participants			
< 65 Years	0	1	3
≥ 65 Years	1	3	2
Age Continuous			
Units: years			
median	70.0	68.0	38.0
full range (min-max)	70 to 70	52 to 78	21 to 77

Sex: Female, Male Units: participants			
Female	0	1	3
Male	1	3	2
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	1	3	3
Unknown or Not Reported	0	1	2
Race/Ethnicity, Customized Units: Subjects			
White	1	0	4
Asian	0	3	1
Black or African American	0	0	0
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Other	0	0	0
Not Collected or Reported	0	1	0
Histology Units: Subjects			
Follicular lymphoma	0	1	0
Diffuse large B-cell lymphoma	1	3	5
Marginal zone lymphoma	0	0	0
Transformed follicular lymphoma	0	0	0
Mantle cell lymphoma	0	0	0
CLL / SLL	0	0	0
Hodgkin lymphoma	0	0	0
Eastern Cooperative Oncology Group (ECOG) Performance Status			
ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead			
Units: Subjects			
0 - Fully Active	0	3	2
1 - Restricted but ambulatory	0	0	2
2 - Ambulatory but unable to work	1	1	1
3 - Limited self-care	0	0	0

<b>Reporting group values</b>	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420	Part 2 Arm B MCL: DUR 1500 + IBR 560	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70
Number of subjects	10	10	10
Age Categorical Units: participants			
< 65 Years	4	2	5
≥ 65 Years	6	8	5
Age Continuous Units: years			
median	68.0	73.5	64.5
full range (min-max)	55 to 73	54 to 84	45 to 75

Sex: Female, Male Units: participants			
Female	3	1	3
Male	7	9	7
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	5	7	6
Unknown or Not Reported	5	3	4
Race/Ethnicity, Customized Units: Subjects			
White	5	6	4
Asian	0	1	1
Black or African American	0	0	1
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Other	0	0	0
Not Collected or Reported	5	3	4
Histology Units: Subjects			
Follicular lymphoma	0	0	10
Diffuse large B-cell lymphoma	0	0	0
Marginal zone lymphoma	0	0	0
Transformed follicular lymphoma	0	0	0
Mantle cell lymphoma	0	10	0
CLL / SLL	10	0	0
Hodgkin lymphoma	0	0	0
Eastern Cooperative Oncology Group (ECOG) Performance Status			
ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead			
Units: Subjects			
0 - Fully Active	8	6	6
1 - Restricted but ambulatory	2	3	3
2 - Ambulatory but unable to work	0	1	1
3 - Limited self-care	0	0	0

<b>Reporting group values</b>	Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70	Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70	Part 2 Arm D FL: DUR 1500
Number of subjects	10	5	5
Age Categorical Units: participants			
< 65 Years	7	2	3
≥ 65 Years	3	3	2
Age Continuous Units: years			
median	60.0	68.0	52.0
full range (min-max)	46 to 71	53 to 79	39 to 71

Sex: Female, Male Units: participants			
Female	4	2	2
Male	6	3	3
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	8	3	2
Unknown or Not Reported	2	1	3
Race/Ethnicity, Customized Units: Subjects			
White	4	4	2
Asian	3	0	0
Black or African American	0	0	0
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Other	1	0	0
Not Collected or Reported	2	1	3
Histology Units: Subjects			
Follicular lymphoma	0	0	5
Diffuse large B-cell lymphoma	10	0	0
Marginal zone lymphoma	0	0	0
Transformed follicular lymphoma	0	0	0
Mantle cell lymphoma	0	0	0
CLL / SLL	0	5	0
Hodgkin lymphoma	0	0	0
Eastern Cooperative Oncology Group (ECOG) Performance Status			
ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead			
Units: Subjects			
0 - Fully Active	7	0	2
1 - Restricted but ambulatory	1	4	2
2 - Ambulatory but unable to work	2	1	1
3 - Limited self-care	0	0	0

<b>Reporting group values</b>	Part 2 Arm D DLBCL: DUR 1500	Part 2 Arm D CLL/SLL: DUR 1500	Part 2 Arm D MCL: DUR 1500
Number of subjects	10	2	5
Age Categorical Units: participants			
< 65 Years	5	1	0
≥ 65 Years	5	1	5
Age Continuous Units: years			
median	61.5	62.0	77.0
full range (min-max)	22 to 76	55 to 69	69 to 80

Sex: Female, Male			
Units: participants			
Female	4	1	2
Male	6	1	3
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	9	2	5
Unknown or Not Reported	1	0	0
Race/Ethnicity, Customized			
Units: Subjects			
White	9	2	4
Asian	0	0	1
Black or African American	0	0	0
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Other	0	0	0
Not Collected or Reported	1	0	0
Histology			
Units: Subjects			
Follicular lymphoma	0	0	0
Diffuse large B-cell lymphoma	10	0	0
Marginal zone lymphoma	0	0	0
Transformed follicular lymphoma	0	0	0
Mantle cell lymphoma	0	0	5
CLL / SLL	0	2	0
Hodgkin lymphoma	0	0	0
Eastern Cooperative Oncology Group (ECOG) Performance Status			
ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead			
Units: Subjects			
0 - Fully Active	3	1	4
1 - Restricted but ambulatory	4	1	1
2 - Ambulatory but unable to work	2	0	0
3 - Limited self-care	1	0	0

Reporting group values	Part 2 Arm D HL: DUR 1500	Total	
Number of subjects	5	106	
Age Categorical			
Units: participants			
< 65 Years	4	44	
≥ 65 Years	1	62	
Age Continuous			
Units: years			
median	51.0		
full range (min-max)	34 to 65	-	

Sex: Female, Male			
Units: participants			
Female	2	35	
Male	3	71	
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	2	
Not Hispanic or Latino	5	76	
Unknown or Not Reported	0	28	
Race/Ethnicity, Customized			
Units: Subjects			
White	5	63	
Asian	0	13	
Black or African American	0	1	
American Indian or Alaska Native	0	0	
Native Hawaiian or Other Pacific Islander	0	0	
Other	0	2	
Not Collected or Reported	0	27	
Histology			
Units: Subjects			
Follicular lymphoma	0	23	
Diffuse large B-cell lymphoma	0	37	
Marginal zone lymphoma	0	5	
Transformed follicular lymphoma	0	1	
Mantle cell lymphoma	0	17	
CLL / SLL	0	18	
Hodgkin lymphoma	5	5	
Eastern Cooperative Oncology Group (ECOG) Performance Status			
ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead			
Units: Subjects			
0 - Fully Active	5	53	
1 - Restricted but ambulatory	0	39	
2 - Ambulatory but unable to work	0	13	
3 - Limited self-care	0	1	

### Subject analysis sets

Subject analysis set title	Part 1, Arm C: DUR 1500 mg + RIT 375 mg/m <sup>2</sup> + BEN 90 mg/m <sup>2</sup>
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 90 mg/m <sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m <sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m <sup>2</sup> Cycle 1 first dose and 500 mg/m <sup>2</sup> for each subsequent dose).	
Subject analysis set title	Part 2, Arm B CLL/SLL: DUR 1500 mg + IBR 420 mG
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Subject analysis set title	Part 2 Arm C DLBCL: DUR + RIT 375 mg/m <sup>2</sup> + BEN 70 mg/m <sup>2</sup>
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m<sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m<sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6.

Subject analysis set title	Arm A: Durvalumab + Lenalidomide ± Rituximab
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm A received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and 10 mg or 20 mg lenalidomide orally once daily on Days 1 to 21 of Cycles 1 to 13 in indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in aggressive NHL, and rituximab 375 mg/m<sup>2</sup> IV weekly in Cycle 1 and on Day 1 of Cycles 2 to 5.

Subject analysis set title	Arm B: Durvalumab + Ibrutinib
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm B received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and 420 or 560 mg ibrutinib orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Subject analysis set title	Arm C: Durvalumab + Bendamustine ± Rituximab
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm C received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, 70 or 90 mg/m<sup>2</sup> bendamustine IV on Days 1 and 2 of Cycles 1 to 6, and rituximab 375 mg/m<sup>2</sup> IV on Day 2 of Cycles 1 to 6 (for CLL the rituximab dose was 375 mg/m<sup>2</sup> Cycle 1 first dose and 500 mg/m<sup>2</sup> for each subsequent dose).

Subject analysis set title	Arm D: Durvalumab Monotherapy
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm D received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13.

Subject analysis set title	Arm D: Durvalumab Monotherapy
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm D received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13.

Subject analysis set title	Arm A: Durvalumab + Lenalidomide ± Rituximab
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm A received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and 10 mg or 20 mg lenalidomide orally once daily on Days 1 to 21 of Cycles 1 to 13 in indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in aggressive NHL, and rituximab 375 mg/m<sup>2</sup> IV weekly in Cycle 1 and on Day 1 of Cycles 2 to 5.

Subject analysis set title	Arm A: Lenalidomide 10 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in Arm A received lenalidomide 10 mg orally once daily on Days 1 to 21 of Cycles 1 to 13 for participants with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and rituximab 375 mg/m<sup>2</sup> IV weekly in Cycle 1 and on Day 1 of Cycles 2 to 5.

Subject analysis set title	Arm A: Lenalidomide 20 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in Arm A received lenalidomide 20 mg orally once daily on Days 1 to 21 of Cycles 1 to 13 for participants with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for

any other reason in participants with aggressive NHL, and durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and rituximab 375 mg/m<sup>2</sup> IV weekly in Cycle 1 and on Day 1 of Cycles 2 to 5.

Subject analysis set title	Arm B: Ibrutinib 420 mg
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Participants assigned to Arm B received 420 mg ibrutinib orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason, and durvalumab 1500 mg IV on Day 1 of Cycles 1 to 13.

Subject analysis set title	Arm B: Ibrutinib 560 mg
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Participants assigned to Arm B received 560 mg ibrutinib orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason, and durvalumab 1500 mg IV on Day 1 of Cycles 1 to 13.

Reporting group values	Part 1, Arm C: DUR 1500 mg + RIT 375 mg/m <sup>2</sup> + BEN 90 mg/m <sup>2</sup>	Part 2, Arm B CLL/SLL: DUR 1500 mg + IBR 420 mg	Part 2 Arm C DLBCL: DUR + RIT 375 mg/m <sup>2</sup> + BEN 70 mg/m <sup>2</sup>
Number of subjects	5	10	10
Age Categorical Units: participants			
< 65 Years	3	4	
≥ 65 Years	2	6	
Age Continuous Units: years			
median	38.0	68.0	30.0
full range (min-max)	21 to 77	55 to 73	6.7 to 65.2
Sex: Female, Male Units: participants			
Female	3	3	
Male	2	7	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	
Not Hispanic or Latino	3	5	
Unknown or Not Reported	2	5	
Race/Ethnicity, Customized Units: Subjects			
White	4	5	
Asian	1	0	
Black or African American	0	0	
American Indian or Alaska Native	0	0	
Native Hawaiian or Other Pacific Islander	0	0	
Other	0	0	
Not Collected or Reported	0	5	
Histology Units: Subjects			
Follicular lymphoma	0	0	
Diffuse large B-cell lymphoma	5	0	
Marginal zone lymphoma	0	0	
Transformed follicular lymphoma	0	0	
Mantle cell lymphoma	0	0	

CLL / SLL Hodgkin lymphoma	0 0	10 0	
Eastern Cooperative Oncology Group ECOG) Performance Status			
ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead			
Units: Subjects			
0 - Fully Active	2	8	
1 - Restricted but ambulatory	2	2	
2 - Ambulatory but unable to work	1	0	
3 - Limited self-care	0	0	

<b>Reporting group values</b>	Arm A: Durvalumab + Lenalidomide ± Rituximab	Arm B: Durvalumab + Ibrutinib	Arm C: Durvalumab + Bendamustine ± Rituximab
Number of subjects	14	27	38
Age Categorical Units: participants			
< 65 Years			
≥ 65 Years			
Age Continuous Units: years median full range (min-max)			
Sex: Female, Male Units: participants			
Female			
Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino			
Not Hispanic or Latino			
Unknown or Not Reported			
Race/Ethnicity, Customized Units: Subjects			
White			
Asian			
Black or African American			
American Indian or Alaska Native			
Native Hawaiian or Other Pacific Islander			
Other			
Not Collected or Reported			
Histology Units: Subjects			
Follicular lymphoma			
Diffuse large B-cell lymphoma			
Marginal zone lymphoma			
Transformed follicular lymphoma			
Mantle cell lymphoma			

CLL / SLL Hodgkin lymphoma			
Eastern Cooperative Oncology Group ECOG) Performance Status			
ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead			
Units: Subjects			
0 - Fully Active 1 - Restricted but ambulatory 2 - Ambulatory but unable to work 3 - Limited self-care			

<b>Reporting group values</b>	Arm D: Durvalumab Monotherapy	Arm D: Durvalumab Monotherapy	Arm A: Durvalumab + Lenalidomide ± Rituximab
Number of subjects	26	25	14
Age Categorical Units: participants			
< 65 Years ≥ 65 Years			
Age Continuous Units: years median full range (min-max)			
Sex: Female, Male Units: participants			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race/Ethnicity, Customized Units: Subjects			
White Asian Black or African American American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Other Not Collected or Reported			
Histology Units: Subjects			
Follicular lymphoma Diffuse large B-cell lymphoma Marginal zone lymphoma Transformed follicular lymphoma Mantle cell lymphoma			

CLL / SLL Hodgkin lymphoma			
Eastern Cooperative Oncology Group ECOG) Performance Status			
ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead			
Units: Subjects			
0 - Fully Active 1 - Restricted but ambulatory 2 - Ambulatory but unable to work 3 - Limited self-care			

<b>Reporting group values</b>	Arm A: Lenalidomide 10 mg	Arm A: Lenalidomide 20 mg	Arm B: Ibrutinib 420 mg
Number of subjects	5	4	13
Age Categorical			
Units: participants			
< 65 Years			
≥ 65 Years			
Age Continuous			
Units: years			
median			
full range (min-max)			
Sex: Female, Male			
Units: participants			
Female			
Male			
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino			
Not Hispanic or Latino			
Unknown or Not Reported			
Race/Ethnicity, Customized			
Units: Subjects			
White			
Asian			
Black or African American			
American Indian or Alaska Native			
Native Hawaiian or Other Pacific Islander			
Other			
Not Collected or Reported			
Histology			
Units: Subjects			
Follicular lymphoma			
Diffuse large B-cell lymphoma			
Marginal zone lymphoma			
Transformed follicular lymphoma			
Mantle cell lymphoma			
CLL / SLL			

Hodgkin lymphoma			
Eastern Cooperative Oncology Group (ECOG) Performance Status			
ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no self-care, confined to bed or chair; • 5 = Dead			
Units: Subjects			
0 - Fully Active 1 - Restricted but ambulatory 2 - Ambulatory but unable to work 3 - Limited self-care			

<b>Reporting group values</b>	Arm B: Ibrutinib 560 mg		
Number of subjects	13		
Age Categorical Units: participants			
< 65 Years ≥ 65 Years			
Age Continuous Units: years median full range (min-max)			
Sex: Female, Male Units: participants			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race/Ethnicity, Customized Units: Subjects			
White Asian Black or African American American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Other Not Collected or Reported			
Histology Units: Subjects			
Follicular lymphoma Diffuse large B-cell lymphoma Marginal zone lymphoma Transformed follicular lymphoma Mantle cell lymphoma CLL / SLL Hodgkin lymphoma			

Eastern Cooperative Oncology Group ECOG) Performance Status			
<p>ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead</p>			
Units: Subjects			
<ul style="list-style-type: none"> <li>0 - Fully Active</li> <li>1 - Restricted but ambulatory</li> <li>2 - Ambulatory but unable to work</li> <li>3 - Limited self-care</li> </ul>			

## End points

### End points reporting groups

Reporting group title	Part 1 Arm A: DUR 1500 + LEN 20
Reporting group description: Participants received durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13 (ie, 12 months) and lenalidomide (LEN) 20 mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for participants with indolent non-Hodgkin's lymphoma (NHL) or for all cycles of treatment period until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL.	
Reporting group title	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375
Reporting group description: Durvalumab (DUR) 1500mg IV infusion on Day 1 of Cycles 1 to 13 and lenalidomide (LEN) 20mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for subjects with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and rituximab (RIT) 375 mg/m <sup>2</sup> IV infusion on Days 2, 8, 15, and 22 of Cycle 1 and on Day 1 of every 28-day cycle from Cycles 2 through 5.	
Reporting group title	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375
Reporting group description: Participants received durvalumab (DUR) 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and lenalidomide (LEN) 10 mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for participants with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and rituximab 375 mg/m <sup>2</sup> IV infusion on Days 2, 8, 15, 22 of Cycle 1 and on Day 1 of every 28-day cycle from Cycles 2 through 5.	
Reporting group title	Part 1 Arm B: DUR 1500 + IBR 420
Reporting group description: Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib (IBR) 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.	
Reporting group title	Part 1 Arm B: DUR 1500 + IBR 560
Reporting group description: Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 560 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.	
Reporting group title	Part 1 Arm C: DUR 1500 + RIT 375
Reporting group description: Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, and rituximab 375 mg/m <sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6 (for participants with CLL the rituximab dose was 375 mg/m <sup>2</sup> Cycle 1 first dose and 500 mg/m <sup>2</sup> for each subsequent dose).	
Reporting group title	Part 1 Arm C: DUR 1500 + BEN 70
Reporting group description: Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and bendamustine (BEN) 70 mg/m <sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6.	
Reporting group title	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70
Reporting group description: Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m <sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m <sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m <sup>2</sup> Cycle 1 first dose and 500 mg/m <sup>2</sup> for each subsequent dose).	
Reporting group title	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90
Reporting group description: Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 90 mg/m <sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m <sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m <sup>2</sup> Cycle 1 first dose and 500 mg/m <sup>2</sup> for each subsequent dose).	
Reporting group title	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420
Reporting group description: Participants with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) received	

durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Reporting group title	Part 2 Arm B MCL: DUR 1500 + IBR 560
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Reporting group description:

Participants with mantle cell lymphoma (MCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 560 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Reporting group title	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70
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Reporting group description:

Participants with follicular lymphoma (FL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m<sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m<sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6.

Reporting group title	Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70
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Reporting group description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m<sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m<sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6.

Reporting group title	Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70
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Reporting group description:

Participants with CLL or SLL received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m<sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m<sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m<sup>2</sup> Cycle 1 first dose and 500 mg/m<sup>2</sup> for each subsequent dose).

Reporting group title	Part 2 Arm D FL: DUR 1500
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Reporting group description:

Participants with follicular lymphoma received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

Reporting group title	Part 2 Arm D DLBCL: DUR 1500
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Reporting group description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

Reporting group title	Part 2 Arm D CLL/SLL: DUR 1500
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Reporting group description:

Participants with CLL or SLL received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

Reporting group title	Part 2 Arm D MCL: DUR 1500
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Reporting group description:

Participants with mantle cell lymphoma (MCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

Reporting group title	Part 2 Arm D HL: DUR 1500
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Reporting group description:

Participants with Hodgkin lymphoma (HL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

Subject analysis set title	Part 1, Arm C: DUR 1500 mg + RIT 375 mg/m <sup>2</sup> + BEN 90 mg/m <sup>2</sup>
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Subject analysis set type	Intention-to-treat
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Subject analysis set description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 90 mg/m<sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m<sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m<sup>2</sup> Cycle 1 first dose and 500 mg/m<sup>2</sup> for each subsequent dose).

Subject analysis set title	Part 2, Arm B CLL/SLL: DUR 1500 mg + IBR 420 mG
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Subject analysis set type	Intention-to-treat
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Subject analysis set description:

Participants with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Subject analysis set title	Part 2 Arm C DLBCL: DUR + RIT 375 mg/m <sup>2</sup> + BEN 70 mg/m <sup>2</sup>
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Subject analysis set type	Intention-to-treat
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Subject analysis set description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m<sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m<sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6.

Subject analysis set title	Arm A: Durvalumab + Lenalidomide ± Rituximab
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm A received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and 10 mg or 20 mg lenalidomide orally once daily on Days 1 to 21 of Cycles 1 to 13 in indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in aggressive NHL, and rituximab 375 mg/m<sup>2</sup> IV weekly in Cycle 1 and on Day 1 of Cycles 2 to 5.

Subject analysis set title	Arm B: Durvalumab + Ibrutinib
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm B received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and 420 or 560 mg ibrutinib orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Subject analysis set title	Arm C: Durvalumab + Bendamustine ± Rituximab
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm C received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, 70 or 90 mg/m<sup>2</sup> bendamustine IV on Days 1 and 2 of Cycles 1 to 6, and rituximab 375 mg/m<sup>2</sup> IV on Day 2 of Cycles 1 to 6 (for CLL the rituximab dose was 375 mg/m<sup>2</sup> Cycle 1 first dose and 500 mg/m<sup>2</sup> for each subsequent dose).

Subject analysis set title	Arm D: Durvalumab Monotherapy
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm D received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13.

Subject analysis set title	Arm D: Durvalumab Monotherapy
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm D received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13.

Subject analysis set title	Arm A: Durvalumab + Lenalidomide ± Rituximab
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm A received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and 10 mg or 20 mg lenalidomide orally once daily on Days 1 to 21 of Cycles 1 to 13 in indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in aggressive NHL, and rituximab 375 mg/m<sup>2</sup> IV weekly in Cycle 1 and on Day 1 of Cycles 2 to 5.

Subject analysis set title	Arm A: Lenalidomide 10 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in Arm A received lenalidomide 10 mg orally once daily on Days 1 to 21 of Cycles 1 to 13 for participants with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and rituximab 375 mg/m<sup>2</sup> IV weekly in Cycle 1 and on Day 1 of Cycles 2 to 5.

Subject analysis set title	Arm A: Lenalidomide 20 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in Arm A received lenalidomide 20 mg orally once daily on Days 1 to 21 of Cycles 1 to 13 for participants with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and rituximab 375 mg/m<sup>2</sup> IV weekly in Cycle 1 and on Day 1 of Cycles 2 to 5.

Subject analysis set title	Arm B: Ibrutinib 420 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm B received 420 mg ibrutinib orally once daily until disease progression,

unacceptable toxicity or discontinuation for any other reason, and durvalumab 1500 mg IV on Day 1 of Cycles 1 to 13.

Subject analysis set title	Arm B: Ibrutinib 560 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm B received 560 mg ibrutinib orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason, and durvalumab 1500 mg IV on Day 1 of Cycles 1 to 13.

### Primary: Part 1: Number of Participants with Dose Limiting Toxicities (DLTs)

End point title	Part 1: Number of Participants with Dose Limiting Toxicities (DLTs) <sup>[1][2]</sup>
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End point description:

Dose limiting toxicities were evaluated during the DLT evaluation period for participants in the dose finding cohorts. The severity grading was determined according to National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) Version 4.03. A DLT is defined as below:  
Hematologic DLT • Grade 4 neutropenia observed for greater than 5 days duration • Grade 3 neutropenia associated with fever ( $\geq 38.5$  °C) of any duration • Grade 4 thrombocytopenia or Grade 3 thrombocytopenia with bleeding, or any requirement for platelets transfusion • Grade 4 anemia, unexplained by underlying disease • Any other grade 4 hematologic toxicity that does not resolve to participant's pretreatment baseline level within 72 hours. Non-Hematologic DLT • Any non-hematological toxicity  $\geq$  Grade 3 except for alopecia and nausea controlled by medical management • Any treatment interruption greater than 2 weeks due to adverse event.

End point type	Primary
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End point timeframe:

Cycle 1 (28 days)

Notes:

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

Justification: Only summary statistics planned for this endpoint.

[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: Endpoints are cohort specific and do not report for all arms.

End point values	Part 1 Arm A: DUR 1500 + LEN 20	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375	Part 1 Arm B: DUR 1500 + IBR 420
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	6	3
Units: Participants	0	3	1	0

End point values	Part 1 Arm B: DUR 1500 + IBR 560	Part 1 Arm C: DUR 1500 + RIT 375	Part 1 Arm C: DUR 1500 + BEN 70	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	0 <sup>[3]</sup>	4
Units: Participants	0	0		0

Notes:

[3] - Unable to calculate due to insufficient number of events.

End point values	Part 1 Arm C: DUR 1500 + RIT 375 + BEN			

	90			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: Participants	1			

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of Participants with Treatment-emergent Adverse Events

End point title	Number of Participants with Treatment-emergent Adverse Events <sup>[4]</sup>
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End point description:

Treatment-emergent adverse events (TEAEs) are defined as adverse events (AEs) occurring or worsening on or after the first dose of any study treatment (durvalumab, lenalidomide, ibrutinib, bendamustine or rituximab) and within 90 days after last dose of durvalumab or 28 days after the last dose of other study drugs, whichever was later, as well as those serious adverse events made known to the investigator at any time thereafter that were suspected of being related to study treatment. The intensity of AEs was graded according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) Version 4.03. For all other AEs not described in the CTCAE criteria, the intensity was assessed by the investigator as mild (Grade 1), moderate (Grade 2), severe (Grade 3), life-threatening (Grade 4), or death (Grade 5).

End point type	Primary
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End point timeframe:

From first dose of any study drug to 90 days after last dose of durvalumab or 28 days after last dose of other study drugs, up to the data cut-off date of 6 March 2019. Maximum time on treatment was 55.4 weeks for DUR and 130 weeks for other study drugs.

Notes:

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

Justification: Only summary statistics planned for this endpoint.

End point values	Part 1 Arm A: DUR 1500 + LEN 20	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375	Part 1 Arm B: DUR 1500 + IBR 420
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	8	3
Units: Participants				
Any TEAE	3	3	8	3
TEAE Related to Any Study Drug	3	3	8	3
CTCAE Grade 3-4 TEAE	1	3	7	2
CTCAE Grade 3-4 TEAE Related to Any Study Drug	1	3	7	1
CTCAE Grade 5 TEAE	0	0	0	0
CTCAE Grade 5 TEAE Related to Any Study Drug	0	0	0	0
Serious TEAE	1	2	4	2
Serious TEAE Related to Any Study Drug	1	2	3	1
TEAE Leading to Discontinuation of Any Study Drug	1	0	3	1
TEAE Leading to Dose Modifications of Study Drug	1	3	3	3

<b>End point values</b>	Part 1 Arm B: DUR 1500 + IBR 560	Part 1 Arm C: DUR 1500 + RIT 375	Part 1 Arm C: DUR 1500 + BEN 70	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	1	4
Units: Participants				
Any TEAE	4	3	1	4
TEAE Related to Any Study Drug	4	3	0	4
CTCAE Grade 3-4 TEAE	3	2	1	3
CTCAE Grade 3-4 TEAE Related to Any Study Drug	1	2	0	2
CTCAE Grade 5 TEAE	0	0	0	0
CTCAE Grade 5 TEAE Related to Any Study Drug	0	0	0	0
Serious TEAE	2	2	1	1
Serious TEAE Related to Any Study Drug	0	1	0	0
TEAE Leading to Discontinuation of Any Study Drug	0	0	0	0
TEAE Leading to Dose Modifications of Study Drug	4	3	1	4

<b>End point values</b>	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420	Part 2 Arm B MCL: DUR 1500 + IBR 560	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	10	10	10
Units: Participants				
Any TEAE	5	10	10	10
TEAE Related to Any Study Drug	5	10	9	10
CTCAE Grade 3-4 TEAE	4	8	10	6
CTCAE Grade 3-4 TEAE Related to Any Study Drug	2	7	6	5
CTCAE Grade 5 TEAE	0	0	1	0
CTCAE Grade 5 TEAE Related to Any Study Drug	0	0	1	0
Serious TEAE	3	6	7	5
Serious TEAE Related to Any Study Drug	1	2	3	3
TEAE Leading to Discontinuation of Any Study Drug	0	0	2	2
TEAE Leading to Dose Modifications of Study Drug	4	8	9	7

<b>End point values</b>	Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70	Part 2 Arm C CLL/SLL: DUR 1500 +RIT 375 +BEN 70	Part 2 Arm D FL: DUR 1500	Part 2 Arm D DLBCL: DUR 1500

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	5	5	10
Units: Participants				
Any TEAE	9	5	5	9
TEAE Related to Any Study Drug	9	5	4	3
CTCAE Grade 3-4 TEAE	9	5	4	7
CTCAE Grade 3-4 TEAE Related to Any Study Drug	7	3	3	2
CTCAE Grade 5 TEAE	0	1	1	4
CTCAE Grade 5 TEAE Related to Any Study Drug	0	0	0	0
Serious TEAE	5	2	4	7
Serious TEAE Related to Any Study Drug	3	1	3	1
TEAE Leading to Discontinuation of Any Study Drug	1	2	1	0
TEAE Leading to Dose Modifications of Study Drug	4	3	2	0

End point values	Part 2 Arm D CLL/SLL: DUR 1500	Part 2 Arm D MCL: DUR 1500	Part 2 Arm D HL: DUR 1500	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	5	5	
Units: Participants				
Any TEAE	2	5	5	
TEAE Related to Any Study Drug	0	3	2	
CTCAE Grade 3-4 TEAE	1	4	3	
CTCAE Grade 3-4 TEAE Related to Any Study Drug	0	1	1	
CTCAE Grade 5 TEAE	0	0	0	
CTCAE Grade 5 TEAE Related to Any Study Drug	0	0	0	
Serious TEAE	0	3	2	
Serious TEAE Related to Any Study Drug	0	0	0	
TEAE Leading to Discontinuation of Any Study Drug	0	1	0	
TEAE Leading to Dose Modifications of Study Drug	0	3	3	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Overall Response Rate (ORR) During Durvalumab Treatment

End point title	Overall Response Rate (ORR) During Durvalumab Treatment <sup>[5]</sup>
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End point description:

For lymphoma participants, response evaluation was based on International Working Group (IWG) response criteria for malignant lymphoma (the Lugano Classification). Overall response rate is defined as the percent of participants with best response of complete response (CR) or partial response (PR). For chronic lymphocytic leukemia participants, response evaluation was based on International Workshop on Chronic Lymphocytic Leukemia (IWCLL) guidelines for diagnosis and treatment of CLL. The

ORR is defined as the percent of participants with best response of CR, complete response with incomplete marrow recovery (CRi), nodular partial response (nPR), PR, or partial response with lymphocytosis (PRL).

End point type	Secondary
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End point timeframe:

Up to 13 cycles (12 months)

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Endpoints are cohort specific and do not report for all arms.

End point values	Part 1 Arm A: DUR 1500 + LEN 20	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375	Part 1 Arm B: DUR 1500 + IBR 420
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	5	3
Units: percentage of participants				
number (confidence interval 95%)	33.3 (0.8 to 90.6)	66.7 (9.4 to 99.2)	80.0 (28.4 to 99.5)	66.7 (9.4 to 99.2)

End point values	Part 1 Arm B: DUR 1500 + IBR 560	Part 1 Arm C: DUR 1500 + RIT 375	Part 1 Arm C: DUR 1500 + BEN 70	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	0 <sup>[6]</sup>	4
Units: percentage of participants				
number (confidence interval 95%)	75.0 (19.4 to 99.4)	33.3 (0.8 to 90.6)	( to )	50.0 (6.8 to 93.2)

Notes:

[6] - Unable to calculate due to insufficient number of events.

End point values	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420	Part 2 Arm B MCL: DUR 1500 + IBR 560	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	9	10	9
Units: percentage of participants				
number (confidence interval 95%)	0 (-99999 to 99999)	88.9 (51.8 to 99.7)	60.0 (26.2 to 87.8)	88.9 (51.8 to 99.7)

End point values	Part 2 Arm C CLL/SLL: DUR 1500 +RIT 375 +BEN 70	Part 2 Arm D FL: DUR 1500	Part 2 Arm D DLBCL: DUR 1500	Part 2 Arm D CLL/SLL: DUR 1500
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	10	2
Units: percentage of participants				
number (confidence interval 95%)	50.0 (6.8 to 93.2)	0 (-99999 to 99999)	0 (-99999 to 99999)	0 (-99999 to 99999)

<b>End point values</b>	Part 2 Arm D MCL: DUR 1500	Part 2 Arm D HL: DUR 1500	Part 2 Arm C DLBCL: DUR + RIT 375 mg/m <sup>2</sup> + BEN 70 mg/m <sup>2</sup>	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	5	5	10	
Units: percentage of participants				
number (confidence interval 95%)	0 (-99999 to 99999)	20.0 (0.5 to 71.6)	30.0 (6.7 to 65.2)	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Overall Response Rate During the Entire Study

End point title	Overall Response Rate During the Entire Study
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End point description:

For lymphoma participants, response evaluation was based on International Working Group (IWG) response criteria for malignant lymphoma (the Lugano Classification) (Cheson, 2014). Overall response rate is defined as the percent of participants with best response of complete response (CR) or partial response (PR). For chronic lymphocytic leukemia participants, response evaluation was based on International Workshop on Chronic Lymphocytic Leukemia (IWCLL) guidelines for diagnosis and treatment of CLL. The ORR is defined as the percentage of participants with best response of CR, complete response with incomplete marrow recovery (CRi), nodular partial response (nPR), PR, or partial response with lymphocytosis (PRL).

-99999/99999 = Not Available

End point type	Secondary
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End point timeframe:

From first dose of any study drug to the end of follow-up, up to the data cutoff date of March 6, 2019; median (minimum, maximum) time on study was 16.7 (0.9, 32.9) months.

<b>End point values</b>	Part 1 Arm A: DUR 1500 + LEN 20	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375	Part 1 Arm B: DUR 1500 + IBR 420
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	5	3
Units: percentage of participants				
number (confidence interval 95%)	66.7 (9.4 to 99.2)	66.7 (9.4 to 99.2)	80.0 (28.4 to 99.5)	66.7 (9.4 to 99.2)

<b>End point values</b>	Part 1 Arm B: DUR 1500 + IBR 560	Part 1 Arm C: DUR 1500 + RIT 375	Part 1 Arm C: DUR 1500 + BEN 70	Part 1 Arm C: DUR 1500 +RIT 375
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				+BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	0 <sup>[7]</sup>	4
Units: percentage of participants				
number (confidence interval 95%)	75.0 (19.4 to 99.4)	33.3 (0.8 to 90.6)	( to )	50.0 (6.8 to 93.2)

Notes:

[7] - Unable to calculate due to insufficient number of events.

<b>End point values</b>	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420	Part 2 Arm B MCL: DUR 1500 + IBR 560	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	9	10	9
Units: percentage of participants				
number (confidence interval 95%)	0 (-99999 to 99999)	100.0 (66.4 to 100.0)	70.0 (34.8 to 93.3)	88.9 (51.8 to 99.7)

<b>End point values</b>	Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70	Part 2 Arm C CLL/SLL: DUR 1500 + RIT 375 + BEN 70	Part 2 Arm D FL: DUR 1500	Part 2 Arm D DLBCL: DUR 1500
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	4	5	10
Units: percentage of participants				
number (confidence interval 95%)	30.0 (6.7 to 65.2)	50.0 (6.8 to 93.2)	0 (-99999 to 99999)	0 (-99999 to 99999)

<b>End point values</b>	Part 2 Arm D CLL/SLL: DUR 1500	Part 2 Arm D MCL: DUR 1500	Part 2 Arm D HL: DUR 1500	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	5	5	
Units: percentage of participants				
number (confidence interval 95%)	0 (-99999 to 99999)	0 (-99999 to 99999)	20.0 (0.5 to 71.6)	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Time to First Response

End point title | Time to First Response

End point description:

Time to response was calculated as the time from first dose of study drug to the first response date (CR or PR for lymphoma participants and CR, CRi, nPR, PR, or PRL for CLL participants).

End point type	Secondary
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End point timeframe:

From first dose of any study drug to the end of follow-up, up to the data cutoff date of March 6, 2019; median (minimum, maximum) time on study was 16.7 (0.9, 32.9) months.

End point values	Part 1 Arm A: DUR 1500 + LEN 20	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375	Part 1 Arm B: DUR 1500 + IBR 420
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	4	2
Units: weeks				
median (full range (min-max))	70.85 (12.1 to 129.6)	12.60 (12.1 to 13.1)	18.20 (11.3 to 36.1)	11.85 (11.4 to 12.3)

End point values	Part 1 Arm B: DUR 1500 + IBR 560	Part 1 Arm C: DUR 1500 + RIT 375	Part 1 Arm C: DUR 1500 + BEN 70	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	1	0 <sup>[8]</sup>	2
Units: weeks				
median (full range (min-max))	13.40 (12.4 to 52.9)	13.00 (13.0 to 13.0)	( to )	13.10 (12.1 to 14.1)

Notes:

[8] - Unable to calculate due to insufficient number of events.

End point values	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420	Part 2 Arm B MCL: DUR 1500 + IBR 560	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 <sup>[9]</sup>	9	7	8
Units: weeks				
median (full range (min-max))	( to )	12.10 (10.9 to 72.9)	12.10 (6.6 to 26.4)	12.35 (10.3 to 15.3)

Notes:

[9] - Unable to calculate due to insufficient number of events.

End point values	Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70	Part 2 Arm C CLL/SLL: DUR 1500 +RIT 375 +BEN 70	Part 2 Arm D FL: DUR 1500	Part 2 Arm D DLBCL: DUR 1500
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	0 <sup>[10]</sup>	0 <sup>[11]</sup>
Units: weeks				
median (full range (min-max))	12.00 (8.7 to 12.1)	12.10 (12.1 to 12.1)	( to )	( to )

Notes:

[10] - Unable to calculate due to insufficient number of events.

[11] - Unable to calculate due to insufficient number of events.

End point values	Part 2 Arm D CLL/SLL: DUR 1500	Part 2 Arm D MCL: DUR 1500	Part 2 Arm D HL: DUR 1500	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 <sup>[12]</sup>	0 <sup>[13]</sup>	1	
Units: weeks				
median (full range (min-max))	( to )	( to )	13.10 (13.1 to 13.1)	

Notes:

[12] - Unable to calculate due to insufficient number of events.

[13] - Unable to calculate due to insufficient number of events.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Kaplan-Meier Estimate of Duration of response

End point title	Kaplan-Meier Estimate of Duration of response
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End point description:

Duration of response is defined for responders only as the time from the first documented response (CR or PR for lymphoma participants or CR, CRi, nPR, PR, or PRL for CLL participants) to disease progression or death (from any cause). For participants with response but no progression, or death, duration of response was censored at the last date that the participant was known to be progression-free.

-99999/99999 = Not Available

End point type	Secondary
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End point timeframe:

From first dose of any study drug to the end of follow-up, up to the data cutoff date of March 6, 2019; median (minimum, maximum) time on study was 16.7 (0.9, 32.9) months.

End point values	Part 1 Arm A: DUR 1500 + LEN 20	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375	Part 1 Arm B: DUR 1500 + IBR 420
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	4	2
Units: weeks				
median (confidence interval 95%)	10.14 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)

End point values	Part 1 Arm B: DUR 1500 + IBR 560	Part 1 Arm C: DUR 1500 + RIT 375	Part 1 Arm C: DUR 1500 + BEN 70	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	1	0 <sup>[14]</sup>	2
Units: weeks				

median (confidence interval 95%)	99999 (-99999 to 99999)	29.29 (-99999 to 99999)	( to )	99999 (-99999 to 99999)
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Notes:

[14] - Unable to calculate due to insufficient number of events.

<b>End point values</b>	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420	Part 2 Arm B MCL: DUR 1500 + IBR 560	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 <sup>[15]</sup>	9	7	8
Units: weeks				
median (confidence interval 95%)	( to )	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)

Notes:

[15] - Unable to calculate due to insufficient number of events.

<b>End point values</b>	Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70	Part 2 Arm C CLL/SLL: DUR 1500 + RIT 375 + BEN 70	Part 2 Arm D FL: DUR 1500	Part 2 Arm D DLBCL: DUR 1500
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	0 <sup>[16]</sup>	0 <sup>[17]</sup>
Units: weeks				
median (confidence interval 95%)	24.14 (9.14 to 26.14)	99999 (-99999 to 99999)	( to )	( to )

Notes:

[16] - Unable to calculate due to insufficient number of events.

[17] - Unable to calculate due to insufficient number of events.

<b>End point values</b>	Part 2 Arm D CLL/SLL: DUR 1500	Part 2 Arm D MCL: DUR 1500	Part 2 Arm D HL: DUR 1500	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 <sup>[18]</sup>	0 <sup>[19]</sup>	1	
Units: weeks				
median (confidence interval 95%)	( to )	( to )	11.14 (-99999 to 99999)	

Notes:

[18] - Unable to calculate due to insufficient number of events.

[19] - Unable to calculate due to insufficient number of events.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Kaplan-Meier Estimate of Progression-free Survival (PFS)

End point title	Kaplan-Meier Estimate of Progression-free Survival (PFS)
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End point description:

Progression-free survival was calculated as the time from first dose of study drug to the first documented progression or death (from any cause) during the entire efficacy evaluation period. For participants with no progression or death, PFS was censored at the last assessment date the participant was known to be progression-free.

-99999/99999 = Not Available

End point type	Secondary
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End point timeframe:

From first dose of any study drug to the end of follow-up, up to the data cutoff date of March 6, 2019; median (minimum, maximum) time on study was 16.7 (0.9, 32.9) months.

<b>End point values</b>	Part 1 Arm A: DUR 1500 + LEN 20	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375	Part 1 Arm B: DUR 1500 + IBR 420
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	8	3
Units: months				
median (confidence interval 95%)	8.41 (5.09 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)

<b>End point values</b>	Part 1 Arm B: DUR 1500 + IBR 560	Part 1 Arm C: DUR 1500 + RIT 375	Part 1 Arm C: DUR 1500 + BEN 70	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	1	4
Units: months				
median (confidence interval 95%)	28.71 (4.50 to 99999)	9.69 (1.64 to 12.68)	1.25 (-99999 to 99999)	3.82 (1.25 to 99999)

<b>End point values</b>	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420	Part 2 Arm B MCL: DUR 1500 + IBR 560	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	10	10	10
Units: months				
median (confidence interval 95%)	2.48 (0.49 to 5.91)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	14.65 (5.75 to 14.65)

<b>End point values</b>	Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70	Part 2 Arm C CLL/SLL: DUR 1500 +RIT 375 +BEN 70	Part 2 Arm D FL: DUR 1500	Part 2 Arm D DLBCL: DUR 1500
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	5	5	10
Units: months				
median (confidence interval 95%)	2.06 (0.76 to 8.28)	99999 (-99999 to 99999)	1.68 (0.69 to 4.63)	1.17 (0.26 to 3.19)

<b>End point values</b>	Part 2 Arm D CLL/SLL: DUR 1500	Part 2 Arm D MCL: DUR 1500	Part 2 Arm D HL: DUR 1500	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	5	5	
Units: months				
median (confidence interval 95%)	2.76 (2.50 to 3.02)	2.33 (0.79 to 10.02)	2.66 (2.56 to 5.98)	

### Statistical analyses

No statistical analyses for this end point

### Secondary: Time to Maximum Plasma Concentration (Tmax) of Durvalumab

End point title	Time to Maximum Plasma Concentration (Tmax) of Durvalumab
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End point description:

End point type	Secondary
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End point timeframe:

Cycle 1, Day 1 (pre-dose and at end of infusion), and 4, 24, 48, 168 (Day 8), 336 (Day 15), and 508 (Day 22) hours after the end of infusion.

<b>End point values</b>	Arm A: Durvalumab + Lenalidomide ± Rituximab	Arm B: Durvalumab + Ibrutinib	Arm C: Durvalumab + Bendamustine + Rituximab	Arm D: Durvalumab Monotherapy
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	14	27	38	26
Units: days				
median (full range (min-max))	0.0510 (0.042 to 1.035)	0.0479 (0.041 to 1.061)	0.0510 (0.042 to 6.788)	0.0420 (0.038 to 1.986)

### Statistical analyses

No statistical analyses for this end point

### Secondary: Maximum Observed Plasma Concentration (Cmax) of Durvalumab

End point title	Maximum Observed Plasma Concentration (Cmax) of Durvalumab
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End point description:

End point type	Secondary
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End point timeframe:

Cycle 1, Day 1 (pre-dose and at end of infusion), and 4, 24, 48, 168 (Day 8), 336 (Day 15), and 508 (Day 22) hours after the end of infusion.

<b>End point values</b>	Arm A: Durvalumab + Lenalidomide ± Rituximab	Arm B: Durvalumab + Ibrutinib	Arm C: Durvalumab + Bendamustine ± Rituximab	Arm D: Durvalumab Monotherapy
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	14	27	38	26
Units: µg/L				
geometric mean (geometric coefficient of variation)	420264.066 (± 22.7)	361906.229 (± 30.1)	331572.478 (± 33.4)	392663.668 (± 41.1)

### Statistical analyses

No statistical analyses for this end point

### Secondary: Area Under the Plasma Concentration-time Curve From Time zero to Infinity (AUCinf) of Durvalumab

End point title	Area Under the Plasma Concentration-time Curve From Time zero to Infinity (AUCinf) of Durvalumab
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End point description:

End point type	Secondary
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End point timeframe:

Cycle 1, Day 1 (pre-dose and at end of infusion), and 4, 24, 48, 168 (Day 8), 336 (Day 15), and 508 (Day 22) hours after the end of infusion.

<b>End point values</b>	Arm A: Durvalumab + Lenalidomide ± Rituximab	Arm B: Durvalumab + Ibrutinib	Arm C: Durvalumab + Bendamustine ± Rituximab	Arm D: Durvalumab Monotherapy
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	14	27	38	25
Units: days*µg/L				
geometric mean (geometric coefficient of variation)	4867431.378 (± 23.3)	5818262.846 (± 42.1)	4762968.345 (± 71.0)	5593532.553 (± 53.0)

### Statistical analyses

No statistical analyses for this end point

### Secondary: Area Under the Plasma Concentration-time Curve from Time Zero to the Last Measurable Concentration (AUClast) of Durvalumab

End point title	Area Under the Plasma Concentration-time Curve from Time Zero to the Last Measurable Concentration (AUClast) of Durvalumab
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End point description:

End point type	Secondary
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End point timeframe:

Cycle 1, Day 1 (pre-dose and at end of infusion), and 4, 24, 48, 168 (Day 8), 336 (Day 15), and 508 (Day 22) hours after the end of infusion.

<b>End point values</b>	Arm A: Durvalumab + Lenalidomide ± Rituximab	Arm B: Durvalumab + Ibrutinib	Arm C: Durvalumab + Bendamustine ± Rituximab	Arm D: Durvalumab Monotherapy
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	14	27	38	26
Units: days*µg/L				
geometric mean (geometric coefficient of variation)	3120149.759 (± 29.5)	3225869.344 (± 31.9)	2670168.397 (± 46.7)	3053060.746 (± 37.8)

### Statistical analyses

No statistical analyses for this end point

### Secondary: Terminal Elimination Phase Half-Life (t<sub>1/2</sub>) of Durvalumab

End point title	Terminal Elimination Phase Half-Life (t <sub>1/2</sub> ) of Durvalumab
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End point description:

End point type	Secondary
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End point timeframe:

Cycle 1, Day 1 (pre-dose and at end of infusion), and 4, 24, 48, 168 (Day 8), 336 (Day 15), and 508 (Day 22) hours after the end of infusion.

<b>End point values</b>	Arm B: Durvalumab + Ibrutinib	Arm C: Durvalumab + Bendamustine ± Rituximab	Arm D: Durvalumab Monotherapy	Arm A: Durvalumab + Lenalidomide ± Rituximab
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	27	38	25	14
Units: days				
geometric mean (geometric coefficient of variation)	17.344 (± 47.3)	16.327 (± 57.4)	15.399 (± 53.5)	11.596 (± 46.6)

### Statistical analyses

No statistical analyses for this end point

## Secondary: Clearance (CL) of Durvalumab

End point title Clearance (CL) of Durvalumab

End point description:

End point type Secondary

End point timeframe:

Cycle 1, Day 1 (pre-dose and at end of infusion), and 4, 24, 48, 168 (Day 8), 336 (Day 15), and 508 (Day 22) hours after the end of infusion.

End point values	Arm A: Durvalumab + Lenalidomide ± Rituximab	Arm B: Durvalumab + Ibrutinib	Arm C: Durvalumab + Bendamustine ± Rituximab	Arm D: Durvalumab Monotherapy
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	14	27	38	25
Units: L/day				
geometric mean (geometric coefficient of variation)	0.3082 (± 23.3)	0.2578 (± 42.1)	0.3149 (± 71.0)	0.2682 (± 53.0)

## Statistical analyses

No statistical analyses for this end point

## Secondary: Volume of Distribution (Vz) of Durvalumab

End point title Volume of Distribution (Vz) of Durvalumab

End point description:

End point type Secondary

End point timeframe:

Cycle 1, Day 1 (pre-dose and at end of infusion), and 4, 24, 48, 168 (Day 8), 336 (Day 15), and 508 (Day 22) hours after the end of infusion.

End point values	Arm A: Durvalumab + Lenalidomide ± Rituximab	Arm B: Durvalumab + Ibrutinib	Arm C: Durvalumab + Bendamustine ± Rituximab	Arm D: Durvalumab Monotherapy
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	14	27	38	25
Units: liters				
geometric mean (geometric coefficient of variation)	5.155 (± 41.9)	6.451 (± 38.3)	7.418 (± 33.7)	5.957 (± 33.0)

## Statistical analyses

No statistical analyses for this end point

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**Secondary: Maximum Observed Plasma Concentration (Cmax) of Lenalidomide**

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End point title	Maximum Observed Plasma Concentration (Cmax) of Lenalidomide
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End point description:  
99999 = Not Available

End point type	Secondary
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End point timeframe:

Cycle 1 Day 1 at predose and 1, 2, 4, and 24 hours post-dose, and Cycle 1 Day 15 at pre-dose, 1, 2, and 4 hours post-dose.

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End point values	Arm A: Lenalidomide 10 mg	Arm A: Lenalidomide 20 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	5	4		
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1	141.881 (± 22.0)	309.917 (± 6.9)		
Cycle 1 Day 15	107.635 (± 40.9)	174.090 (± 99999)		

**Statistical analyses**

No statistical analyses for this end point

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**Secondary: Time to Maximum Observed Plasma Concentration (Tmax) of Lenalidomide**

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End point title	Time to Maximum Observed Plasma Concentration (Tmax) of Lenalidomide
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End point description:

End point type	Secondary
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End point timeframe:

Cycle 1 Day 1 at predose and 1, 2, 4, and 24 hours post-dose, and Cycle 1 Day 15 at pre-dose, 1, 2, and 4 hours post-dose.

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<b>End point values</b>	Arm A: Lenalidomide 10 mg	Arm A: Lenalidomide 20 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	5	4		
Units: hours				
median (full range (min-max))				
Cycle 1 Day 1	1.9500 (1.000 to 3.917)	1.1667 (1.000 to 1.433)		
Cycle 1 Day 15	3.0333 (1.233 to 4.000)	1.000 (1.000 to 1.000)		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Area Under the Plasma Concentration-time Curve from Time Zero to the Last Measurable Concentration (AUClast) of Lenalidomide

End point title	Area Under the Plasma Concentration-time Curve from Time Zero to the Last Measurable Concentration (AUClast) of Lenalidomide
End point description:	
End point type	Secondary
End point timeframe:	Cycle 1 Day 1 at predose and 1, 2, 4, and 24 hours post-dose

<b>End point values</b>	Arm A: Lenalidomide 10 mg	Arm A: Lenalidomide 20 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	5	4		
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)	789.297 ( $\pm$ 84.3)	805.299 ( $\pm$ 56.0)		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Maximum Observed Plasma Concentration (Cmax) of Ibrutinib

End point title	Maximum Observed Plasma Concentration (Cmax) of Ibrutinib
End point description:	
End point type	Secondary
End point timeframe:	Cycle 1 Day 1 at predose and 1, 2, 4, and 24 hours post-dose, and Cycle 1 Day 15 at pre-dose, 1, 2,

and 4 hours post-dose.

<b>End point values</b>	Arm B: Ibrutinib 420 mg	Arm B: Ibrutinib 560 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	13	13		
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1	129.704 (± 98.0)	67.728 (± 197.9)		
Cycle 1 Day 15	86.840 (± 136.9)	72.436 (± 166.3)		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Area Under the Plasma Concentration-time Curve from Time Zero to the Last Measurable Concentration (AUClast) of Ibrutinib

End point title	Area Under the Plasma Concentration-time Curve from Time Zero to the Last Measurable Concentration (AUClast) of Ibrutinib
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End point description:

End point type	Secondary
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End point timeframe:

Cycle 1 Day 1 at predose and 1, 2, 4, and 24 hours post-dose

<b>End point values</b>	Arm B: Ibrutinib 420 mg	Arm B: Ibrutinib 560 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	13	13		
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)	586.396 (± 117.2)	436.855 (± 246.5)		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in Soluble Programmed Cell Death Ligand-1 (sPD-

## L1) Concentration

End point title	Change from Baseline in Soluble Programmed Cell Death Ligand-1 (sPD-L1) Concentration
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End point description:

Change from baseline in sPD-L1 could not be calculated as all post-baseline samples were below the lower limit of quantification (<15.60 pg/mL).

End point type	Secondary
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End point timeframe:

Baseline (Cycle 1 Day 1 predose) and Day 1 of Cycles 2 to 13

End point values	Part 1 Arm A: DUR 1500 + LEN 20	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375	Part 1 Arm B: DUR 1500 + IBR 420
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 <sup>[20]</sup>	0 <sup>[21]</sup>	0 <sup>[22]</sup>	0 <sup>[23]</sup>
Units: pg/mL				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[20] - Unable to calculate due to insufficient number of events.

[21] - Unable to calculate due to insufficient number of events.

[22] - Unable to calculate due to insufficient number of events.

[23] - Unable to calculate due to insufficient number of events.

End point values	Part 1 Arm B: DUR 1500 + IBR 560	Part 1 Arm C: DUR 1500 + RIT 375	Part 1 Arm C: DUR 1500 + BEN 70	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 <sup>[24]</sup>	0 <sup>[25]</sup>	0 <sup>[26]</sup>	0 <sup>[27]</sup>
Units: pg/mL				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[24] - Unable to calculate due to insufficient number of events.

[25] - Unable to calculate due to insufficient number of events.

[26] - Unable to calculate due to insufficient number of events.

[27] - Unable to calculate due to insufficient number of events.

End point values	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420	Part 2 Arm B MCL: DUR 1500 + IBR 560	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 <sup>[28]</sup>	0 <sup>[29]</sup>	0 <sup>[30]</sup>	0 <sup>[31]</sup>
Units: pg/mL				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[28] - Unable to calculate due to insufficient number of events.

[29] - Unable to calculate due to insufficient number of events.

[30] - Unable to calculate due to insufficient number of events.

[31] - Unable to calculate due to insufficient number of events.

<b>End point values</b>	Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70	Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70	Part 2 Arm D FL: DUR 1500	Part 2 Arm D DLBCL: DUR 1500
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 <sup>[32]</sup>	0 <sup>[33]</sup>	0 <sup>[34]</sup>	0 <sup>[35]</sup>
Units: pg/mL				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[32] - Unable to calculate due to insufficient number of events.

[33] - Unable to calculate due to insufficient number of events.

[34] - Unable to calculate due to insufficient number of events.

[35] - Unable to calculate due to insufficient number of events.

<b>End point values</b>	Part 2 Arm D CLL/SLL: DUR 1500	Part 2 Arm D MCL: DUR 1500	Part 2 Arm D HL: DUR 1500	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 <sup>[36]</sup>	0 <sup>[37]</sup>	0 <sup>[38]</sup>	
Units: pg/mL				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[36] - Unable to calculate due to insufficient number of events.

[37] - Unable to calculate due to insufficient number of events.

[38] - Unable to calculate due to insufficient number of events.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Time to Maximum Observed Plasma Concentration (Tmax) of Ibrutinib

End point title	Time to Maximum Observed Plasma Concentration (Tmax) of Ibrutinib
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End point description:

End point type	Secondary
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End point timeframe:

Cycle 1 Day 1 at predose and 1, 2, 4, and 24 hours post-dose, and Cycle 1 Day 15 at pre-dose, 1, 2, and 4 hours post-dose.

<b>End point values</b>	Arm B: Ibrutinib 420 mg	Arm B: Ibrutinib 560 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	13	13		
Units: hours				
median (full range (min-max))				
Cycle 1 Day 1	2.000 (0.000 to 4.367)	1.9333 (0.933 to 3.917)		
Cycle 1 Day 15	1.8833 (1.000 to 4.000)	2.000 (1.000 to 4.083)		

## Statistical analyses

No statistical analyses for this end point

### Post-hoc: Number of Participants with Treatment-emergent Adverse Events (TEAEs) - Extended Collection

End point title	Number of Participants with Treatment-emergent Adverse Events (TEAEs) - Extended Collection
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End point description:

TEAEs defined as AEs occurring or worsening on or after first dose of any study treatment (durvalumab, lenalidomide, ibrutinib, bendamustine or rituximab) and within 90 days after last dose of durvalumab or 28 days after the last dose of other study drugs, whichever was later, as well as those serious adverse events made known to the investigator at any time thereafter that were suspected of being related to study treatment. Intensity of AEs graded according to the NCI CTCAE V. 4.03. For all other AEs not described in the CTCAE criteria, the intensity was assessed by investigator as mild (Grade 1), moderate (Grade 2), severe (Grade 3), life-threatening (Grade 4), or death (Grade 5). This outcome measure represents an updated version of the primary endpoint to include additional data collection that has occurred after the primary completion date (assessments made until August 21, 2022).

End point type	Post-hoc
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End point timeframe:

From first dose of any study drug to 90 days after last dose of durvalumab or 28 days after last dose of other study drugs, up to the study completion date of August 21, 2022 (up to approximately 75 months).

End point values	Part 1 Arm A: DUR 1500 + LEN 20	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375	Part 1 Arm B: DUR 1500 + IBR 420
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	8	3
Units: Participants				
Any TEAE	3	3	8	3
TEAE Related to Any Study Drug	3	3	8	3
CTCAE Grade 3-4 TEAE	1	3	7	2
CTCAE Grade 3-4 TEAE Related to Any Study Drug	1	3	7	1
CTCAE Grade 5 TEAE	0	0	0	0
CTCAE Grade 5 TEAE Related to Any Study Drug	0	0	0	0
Serious TEAE	1	2	4	2
Serious TEAE Related to Any Study Drug	1	2	3	1
TEAE Leading to Discontinuation of Any Study Drug	1	0	3	1
TEAE Leading to Dose Modifications of Study Drug	1	3	5	3

<b>End point values</b>	Part 1 Arm B: DUR 1500 + IBR 560	Part 1 Arm C: DUR 1500 + RIT 375	Part 1 Arm C: DUR 1500 + BEN 70	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	1	4
Units: Participants				
Any TEAE	4	3	1	4
TEAE Related to Any Study Drug	4	3	0	4
CTCAE Grade 3-4 TEAE	4	2	1	3
CTCAE Grade 3-4 TEAE Related to Any Study Drug	1	2	0	2
CTCAE Grade 5 TEAE	0	0	0	0
CTCAE Grade 5 TEAE Related to Any Study Drug	0	0	0	0
Serious TEAE	3	2	1	1
Serious TEAE Related to Any Study Drug	0	1	0	0
TEAE Leading to Discontinuation of Any Study Drug	0	0	0	0
TEAE Leading to Dose Modifications of Study Drug	4	3	1	4

<b>End point values</b>	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420	Part 2 Arm B MCL: DUR 1500 + IBR 560	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	10	10	10
Units: Participants				
Any TEAE	5	10	10	10
TEAE Related to Any Study Drug	5	10	9	10
CTCAE Grade 3-4 TEAE	4	9	10	6
CTCAE Grade 3-4 TEAE Related to Any Study Drug	2	8	6	5
CTCAE Grade 5 TEAE	0	0	1	0
CTCAE Grade 5 TEAE Related to Any Study Drug	0	0	1	0
Serious TEAE	3	6	7	5
Serious TEAE Related to Any Study Drug	1	3	3	3
TEAE Leading to Discontinuation of Any Study Drug	0	0	2	2
TEAE Leading to Dose Modifications of Study Drug	4	9	9	7

<b>End point values</b>	Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70	Part 2 Arm C CLL/SLL: DUR 1500 +RIT 375 +BEN 70	Part 2 Arm D FL: DUR 1500	Part 2 Arm D DLBCL: DUR 1500
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	5	5	10
Units: Participants				
Any TEAE	9	5	5	9
TEAE Related to Any Study Drug	9	5	4	3
CTCAE Grade 3-4 TEAE	9	5	4	7
CTCAE Grade 3-4 TEAE Related to Any Study Drug	7	3	3	2
CTCAE Grade 5 TEAE	0	1	1	4
CTCAE Grade 5 TEAE Related to Any Study Drug	0	0	0	0
Serious TEAE	5	2	4	7
Serious TEAE Related to Any Study Drug	3	1	3	1
TEAE Leading to Discontinuation of Any Study Drug	1	2	1	0
TEAE Leading to Dose Modifications of Study Drug	4	3	2	0

<b>End point values</b>	Part 2 Arm D CLL/SLL: DUR 1500	Part 2 Arm D MCL: DUR 1500	Part 2 Arm D HL: DUR 1500	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	5	5	
Units: Participants				
Any TEAE	2	5	5	
TEAE Related to Any Study Drug	0	3	2	
CTCAE Grade 3-4 TEAE	1	4	3	
CTCAE Grade 3-4 TEAE Related to Any Study Drug	0	1	1	
CTCAE Grade 5 TEAE	0	0	0	
CTCAE Grade 5 TEAE Related to Any Study Drug	0	0	0	
Serious TEAE	0	3	2	
Serious TEAE Related to Any Study Drug	0	0	0	
TEAE Leading to Discontinuation of Any Study Drug	0	1	0	
TEAE Leading to Dose Modifications of Study Drug	0	3	3	

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

SAEs and NSAEs assessed from first dose to 90 days from last dose of durva or 28 days from last dose of lenalidomide, ibrutinib, rituximab, bendamustine, or IFRT, whichever occurs later (up to approximately 75 months)

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
Dictionary version	22.0

### Reporting groups

Reporting group title	Part 1 Arm A: DUR 1500 + LEN 20 + RIT 375
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Reporting group description:

Participants received durvalumab (DUR) 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and lenalidomide (LEN) 20 mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for participants with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and rituximab (RIT) 375 mg/m<sup>2</sup> IV infusion on Days 2, 8, 15, and 22 of Cycle 1 and on Day 1 of every 28-day cycle from Cycles 2 through 5.

Reporting group title	Part 1 Arm A: DUR 1500 + LEN 20
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Reporting group description:

Participants received durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13 (ie, 12 months) and lenalidomide (LEN) 20 mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for participants with indolent non-Hodgkin's lymphoma (NHL) or for all cycles of treatment period until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL.

Reporting group title	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 70
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Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m<sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m<sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m<sup>2</sup> Cycle 1 first dose and 500 mg/m<sup>2</sup> for each subsequent dose).

Reporting group title	Part 1 Arm C: DUR 1500 + BEN 70
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Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and bendamustine (BEN) 70 mg/m<sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6.

Reporting group title	Part 1 Arm C: DUR 1500 + RIT 375
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Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, and rituximab 375 mg/m<sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6 (for participants with CLL the rituximab dose was 375 mg/m<sup>2</sup> Cycle 1 first dose and 500 mg/m<sup>2</sup> for each subsequent dose).

Reporting group title	Part 1 Arm B: DUR 1500 + IBR 560
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Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 560 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Reporting group title	Part 1 Arm B: DUR 1500 + IBR 420
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Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib (IBR) 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Reporting group title	Part 1 Arm A: DUR 1500 + LEN 10 + RIT 375
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Reporting group description:

Participants received durvalumab (DUR) 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and lenalidomide (LEN) 10 mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for participants with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and rituximab 375 mg/m<sup>2</sup> IV infusion on Days 2, 8, 15, 22 of Cycle

1 and on Day 1 of every 28-day cycle from Cycles 2 through 5.

Reporting group title	Part 2, Arm D CLL/SLL: DUR 1500 mg
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Reporting group description:

Participants with CLL or SLL received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

Reporting group title	Part 2, Arm D MCL: DUR 1500 mg
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Reporting group description:

Participants with mantle cell lymphoma (MCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

Reporting group title	Part 2, Arm D DLBCL: DUR 1500 mg
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Reporting group description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

Reporting group title	Part 2 Arm D FL: DUR 1500
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Reporting group description:

Participants with follicular lymphoma received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

Reporting group title	Part 2 Arm C CLL/SLL: DUR 1500 + RIT 375 + BEN 70
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Reporting group description:

Participants with CLL or SLL received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m<sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m<sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m<sup>2</sup> Cycle 1 first dose and 500 mg/m<sup>2</sup> for each subsequent dose).

Reporting group title	Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70
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Reporting group description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m<sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m<sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6.

Reporting group title	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70
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Reporting group description:

Participants with follicular lymphoma (FL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m<sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m<sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6.

Reporting group title	Part 2 Arm B MCL: DUR 1500 + IBR 560
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Reporting group description:

Participants with mantle cell lymphoma (MCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 560 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Reporting group title	Part 2, Arm D HL: DUR 1500 mg
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Reporting group description:

Participants with Hodgkin lymphoma (HL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

Reporting group title	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90
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Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 90 mg/m<sup>2</sup> IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m<sup>2</sup> IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m<sup>2</sup> Cycle 1 first dose and 500 mg/m<sup>2</sup> for each subsequent dose).

Reporting group title	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420
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Reporting group description:

Participants with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

<b>Serious adverse events</b>	Part 1 Arm A: DUR 1500 + LEN 20 + RIT 375	Part 1 Arm A: DUR 1500 + LEN 20	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 70
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	1 / 3 (33.33%)	1 / 4 (25.00%)
number of deaths (all causes)	1	1	3
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
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
Prostate 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
Squamous cell carcinoma of skin			
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
Squamous cell carcinoma of lung			
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			
Jugular 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
Hypotension			
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
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
<b>General disorders and administration site conditions</b>			
<b>Asthenia</b>			
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
<b>General physical health deterioration</b>			
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
<b>Malaise</b>			
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
<b>Generalised oedema</b>			
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
<b>Multiple organ dysfunction syndrome</b>			
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
<b>Pyrexia</b>			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (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
<b>Pain</b>			
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
<b>Immune system disorders</b>			

Cytokine release 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
<b>Respiratory, thoracic and mediastinal disorders</b>			
Dyspnoea 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
Organising pneumonia 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
Pneumonitis 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
<b>Investigations</b>			
Electrocardiogram QT prolonged 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
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

General physical condition abnormal 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			
Post procedural 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
Cardiac disorders			
Acute coronary 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
Atrial fibrillation 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 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
Myocardial infarction 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			
Cerebral ischaemia 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
Syncope			

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
<b>Blood and lymphatic system disorders</b>			
<b>Anaemia</b>			
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
<b>Cytopenia</b>			
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
<b>Febrile neutropenia</b>			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (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
<b>Neutropenia</b>			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (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
<b>Pancytopenia</b>			
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
<b>Thrombocytopenia</b>			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (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
<b>Gastrointestinal disorders</b>			
<b>Abdominal pain</b>			
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
<b>Aptyalism</b>			

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 wall 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
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
Colon dysplasia			
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
Gastric 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
Gastrointestinal perforation			
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
Haematemesis			
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
Small intestinal 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
Small intestinal 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
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
Hepatobiliary disorders			
Hepatitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	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			
Drug reaction with eosinophilia and systemic symptoms			
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	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
Endocrine disorders			
Adrenal insufficiency			

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
<b>Musculoskeletal and connective tissue disorders</b>			
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
<b>Infections and infestations</b>			
Bronchiolitis			
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
Bronchitis			
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
Bronchitis viral			
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
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
Influenza			
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

Lower respiratory tract infection viral			
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	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
Neutropenic 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
Parainfluenzae virus 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
Pleural infection bacterial			
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	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
Septic 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
Sepsis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (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
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
<b>Sinusitis</b>			
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
<b>Streptococcal infection</b>			
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
<b>Vascular device infection</b>			
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
<b>Metabolism and nutrition disorders</b>			
<b>Dehydration</b>			
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
<b>Hyponatraemia</b>			
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

<b>Serious adverse events</b>	Part 1 Arm C: DUR 1500 + BEN 70	Part 1 Arm C: DUR 1500 + RIT 375	Part 1 Arm B: DUR 1500 + IBR 560
<b>Total subjects affected by serious adverse events</b>			
subjects affected / exposed	1 / 1 (100.00%)	2 / 3 (66.67%)	3 / 4 (75.00%)
number of deaths (all causes)	1	2	3
number of deaths resulting from adverse events	0	0	0
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>			
Basal cell carcinoma			

subjects affected / exposed	0 / 1 (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
Prostate cancer			
subjects affected / exposed	0 / 1 (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
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 1 (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
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 1 (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			
Jugular vein thrombosis			
subjects affected / exposed	0 / 1 (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
Hypotension			
subjects affected / exposed	0 / 1 (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 / 1 (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			
Asthenia			
subjects affected / exposed	0 / 1 (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 physical health deterioration			
subjects affected / exposed	0 / 1 (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 / 1 (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
Generalised oedema			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 4 (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
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 1 (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
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 4 (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
Pain			
subjects affected / exposed	0 / 1 (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			
Cytokine release syndrome			
subjects affected / exposed	0 / 1 (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 / 1 (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

Organising pneumonia			
subjects affected / exposed	0 / 1 (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 / 1 (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
Pneumonitis			
subjects affected / exposed	0 / 1 (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 / 1 (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			
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 1 (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
Alanine aminotransferase increased			
subjects affected / exposed	0 / 1 (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 physical condition abnormal			
subjects affected / exposed	0 / 1 (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			
Post procedural haemorrhage			
subjects affected / exposed	0 / 1 (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			
Acute coronary syndrome			
subjects affected / exposed	0 / 1 (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
Atrial fibrillation			
subjects affected / exposed	0 / 1 (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 failure			
subjects affected / exposed	0 / 1 (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
Myocardial infarction			
subjects affected / exposed	0 / 1 (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			
Cerebral ischaemia			
subjects affected / exposed	0 / 1 (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
Syncope			
subjects affected / exposed	0 / 1 (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 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytopenia			

subjects affected / exposed	0 / 1 (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
<b>Febrile neutropenia</b>			
subjects affected / exposed	0 / 1 (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
<b>Neutropenia</b>			
subjects affected / exposed	0 / 1 (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
<b>Pancytopenia</b>			
subjects affected / exposed	0 / 1 (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
<b>Thrombocytopenia</b>			
subjects affected / exposed	0 / 1 (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
<b>Gastrointestinal disorders</b>			
<b>Abdominal pain</b>			
subjects affected / exposed	0 / 1 (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
<b>Aptyalism</b>			
subjects affected / exposed	0 / 1 (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
<b>Abdominal wall haematoma</b>			
subjects affected / exposed	0 / 1 (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
<b>Diarrhoea</b>			

subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 4 (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
Colon dysplasia			
subjects affected / exposed	0 / 1 (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
Gastric haemorrhage			
subjects affected / exposed	0 / 1 (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 perforation			
subjects affected / exposed	0 / 1 (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
Haematemesis			
subjects affected / exposed	0 / 1 (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 / 1 (0.00%)	1 / 3 (33.33%)	0 / 4 (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
Small intestinal haemorrhage			
subjects affected / exposed	0 / 1 (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 intestinal obstruction			
subjects affected / exposed	0 / 1 (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 / 1 (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
<b>Hepatobiliary disorders</b>			
Hepatitis			
subjects affected / exposed	0 / 1 (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
Hyperbilirubinaemia			
subjects affected / exposed	0 / 1 (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
<b>Skin and subcutaneous tissue disorders</b>			
Drug reaction with eosinophilia and systemic symptoms			
subjects affected / exposed	0 / 1 (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
<b>Renal and urinary disorders</b>			
Acute kidney injury			
subjects affected / exposed	1 / 1 (100.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Endocrine disorders</b>			
Adrenal insufficiency			
subjects affected / exposed	0 / 1 (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
<b>Musculoskeletal and connective tissue disorders</b>			
Flank pain			
subjects affected / exposed	0 / 1 (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
<b>Infections and infestations</b>			
Bronchiolitis			

subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 4 (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
<b>Bronchitis</b>			
subjects affected / exposed	0 / 1 (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
<b>Bronchitis viral</b>			
subjects affected / exposed	0 / 1 (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
<b>Cellulitis</b>			
subjects affected / exposed	0 / 1 (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
<b>Influenza</b>			
subjects affected / exposed	0 / 1 (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
<b>Lower respiratory tract infection</b>			
subjects affected / exposed	0 / 1 (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
<b>Lower respiratory tract infection viral</b>			
subjects affected / exposed	0 / 1 (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
<b>Lung infection</b>			
subjects affected / exposed	0 / 1 (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
<b>Neutropenic sepsis</b>			

subjects affected / exposed	0 / 1 (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
Parainfluenzae virus infection			
subjects affected / exposed	0 / 1 (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 infection bacterial			
subjects affected / exposed	0 / 1 (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	0 / 1 (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
Septic shock			
subjects affected / exposed	0 / 1 (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
Sepsis			
subjects affected / exposed	1 / 1 (100.00%)	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
Skin infection			
subjects affected / exposed	0 / 1 (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
Sinusitis			
subjects affected / exposed	0 / 1 (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
Streptococcal infection			

subjects affected / exposed	0 / 1 (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
<b>Vascular device infection</b>			
subjects affected / exposed	0 / 1 (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
<b>Metabolism and nutrition disorders</b>			
<b>Dehydration</b>			
subjects affected / exposed	0 / 1 (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
<b>Hyponatraemia</b>			
subjects affected / exposed	0 / 1 (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

<b>Serious adverse events</b>	Part 1 Arm B: DUR 1500 + IBR 420	Part 1 Arm A: DUR 1500 + LEN 10 + RIT 375	Part 2, Arm D CLL/SLL: DUR 1500 mg
<b>Total subjects affected by serious adverse events</b>			
subjects affected / exposed	2 / 3 (66.67%)	4 / 8 (50.00%)	0 / 2 (0.00%)
number of deaths (all causes)	0	2	0
number of deaths resulting from adverse events	0	0	0
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>			
<b>Basal cell carcinoma</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
<b>Prostate cancer</b>			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (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
<b>Squamous cell carcinoma of skin</b>			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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			
Jugular vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	1 / 8 (12.50%)	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
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 physical health deterioration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Generalised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	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
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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			
Cytokine release syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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
Organising pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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

Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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	0 / 3 (0.00%)	0 / 8 (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			
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 physical condition abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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			
Post procedural haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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			
Acute coronary syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
<b>Cardiac failure</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
<b>Myocardial infarction</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
<b>Nervous system disorders</b>			
<b>Cerebral ischaemia</b>			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	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
<b>Syncope</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
<b>Blood and lymphatic system disorders</b>			
<b>Anaemia</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
<b>Cytopenia</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
<b>Febrile neutropenia</b>			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	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
<b>Neutropenia</b>			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
<b>Pancytopenia</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
<b>Thrombocytopenia</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
<b>Gastrointestinal disorders</b>			
<b>Abdominal pain</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
<b>Aptyalism</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
<b>Abdominal wall haematoma</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
<b>Diarrhoea</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
<b>Colon dysplasia</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
<b>Gastric haemorrhage</b>			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 perforation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
Haematemesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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 intestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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			
Hepatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
Hyperbilirubinaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
<b>Skin and subcutaneous tissue disorders</b>			
Drug reaction with eosinophilia and systemic symptoms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
<b>Renal and urinary disorders</b>			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
<b>Endocrine disorders</b>			
Adrenal insufficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
<b>Musculoskeletal and connective tissue disorders</b>			
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
<b>Infections and infestations</b>			
Bronchiolitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	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
Bronchitis viral			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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 viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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	1 / 3 (33.33%)	0 / 8 (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
Neutropenic sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
Parainfluenzae virus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural infection bacterial			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	1 / 8 (12.50%)	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
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
Streptococcal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 device infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	1 / 8 (12.50%)	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

<b>Serious adverse events</b>	Part 2, Arm D MCL: DUR 1500 mg	Part 2, Arm D DLBCL: DUR 1500 mg	Part 2 Arm D FL: DUR 1500
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 5 (80.00%)	8 / 10 (80.00%)	4 / 5 (80.00%)
number of deaths (all causes)	4	9	4
number of deaths resulting from adverse events	0	4	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Jugular vein thrombosis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	2 / 5 (40.00%)	2 / 10 (20.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pyrexia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pain</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Immune system disorders</b>			
<b>Cytokine release syndrome</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Respiratory, thoracic and mediastinal disorders</b>			
<b>Dyspnoea</b>			
subjects affected / exposed	1 / 5 (20.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
<b>Organising pneumonia</b>			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (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
<b>Pleural effusion</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pneumonitis</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pulmonary embolism</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Investigations			
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical condition abnormal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Post procedural haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Myocardial infarction			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Nervous system disorders</b>			
Cerebral ischaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Blood and lymphatic system disorders</b>			
Anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
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 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastrointestinal disorders</b>			
<b>Abdominal pain</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Aptyalism</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Abdominal wall haematoma</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Diarrhoea</b>			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Colon dysplasia</b>			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastric haemorrhage</b>			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastrointestinal perforation</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Haematemesis</b>			

subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Rectal haemorrhage</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Small intestinal haemorrhage</b>			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Small intestinal obstruction</b>			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Vomiting</b>			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hepatobiliary disorders</b>			
<b>Hepatitis</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hyperbilirubinaemia</b>			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Skin and subcutaneous tissue disorders</b>			
<b>Drug reaction with eosinophilia and systemic symptoms</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Flank pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis viral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural infection bacterial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Septic shock			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Sepsis</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Skin infection</b>			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Sinusitis</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Streptococcal infection</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Vascular device infection</b>			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Metabolism and nutrition disorders</b>			
<b>Dehydration</b>			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hyponatraemia</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

<b>Serious adverse events</b>	Part 2 Arm C	Part 2 Arm C DLBCL:	Part 2 Arm C FL:
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	CLL/SLL: DUR 1500 + RIT 375 + BEN 70	DUR 1500 + RIT 375 + BEN 70	DUR 1500 + RIT 375 + BEN 70
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 5 (40.00%)	5 / 10 (50.00%)	5 / 10 (50.00%)
number of deaths (all causes)	2	9	0
number of deaths resulting from adverse events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
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			
Jugular vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
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 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>General disorders and administration site conditions</b>			
<b>Asthenia</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>General physical health deterioration</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Malaise</b>			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (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
<b>Generalised oedema</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Multiple organ dysfunction syndrome</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pyrexia</b>			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (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
<b>Pain</b>			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (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
<b>Immune system disorders</b>			

Cytokine release syndrome subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Respiratory, thoracic and mediastinal disorders</b>			
Dyspnoea subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organising pneumonia subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
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 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
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 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (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
<b>Investigations</b>			
Electrocardiogram QT prolonged subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alanine aminotransferase increased subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

General physical condition abnormal subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
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			
Post procedural haemorrhage subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 10 (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			
Cerebral ischaemia subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Blood and lymphatic system disorders</b>			
<b>Anaemia</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cytopenia</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Febrile neutropenia</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Neutropenia</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pancytopenia</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Thrombocytopenia</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastrointestinal disorders</b>			
<b>Abdominal pain</b>			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (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
<b>Aptyalism</b>			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
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 wall haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
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 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon dysplasia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
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 perforation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
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 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
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 intestinal haemorrhage			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
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 intestinal obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
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 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
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			
Hepatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
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			
Drug reaction with eosinophilia and systemic symptoms			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
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 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Musculoskeletal and connective tissue disorders</b>			
Flank pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Infections and infestations</b>			
Bronchiolitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis viral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 10 (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
Influenza			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
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 viral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
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 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (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
Neutropenic sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
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 infection bacterial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
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 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Skin infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Sinusitis</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Streptococcal infection</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Vascular device infection</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Metabolism and nutrition disorders</b>			
<b>Dehydration</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hyponatraemia</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

<b>Serious adverse events</b>	Part 2 Arm B MCL: DUR 1500 + IBR 560	Part 2, Arm D HL: DUR 1500 mg	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90
<b>Total subjects affected by serious adverse events</b>			
subjects affected / exposed	7 / 10 (70.00%)	2 / 5 (40.00%)	3 / 5 (60.00%)
number of deaths (all causes)	2	4	4
number of deaths resulting from adverse events	1	0	0
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>			
Basal cell carcinoma			

subjects affected / exposed	2 / 10 (20.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Jugular vein thrombosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 10 (0.00%)	1 / 5 (20.00%)	0 / 5 (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
Superior vena cava syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

General physical health deterioration			
subjects affected / exposed	0 / 10 (0.00%)	1 / 5 (20.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 10 (10.00%)	2 / 5 (40.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Organising pneumonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (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	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alanine aminotransferase increased			
subjects affected / exposed	2 / 10 (20.00%)	0 / 5 (0.00%)	0 / 5 (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
General physical condition abnormal			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Post procedural haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral ischaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytopenia			

subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Febrile neutropenia</b>			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Neutropenia</b>			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pancytopenia</b>			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Thrombocytopenia</b>			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastrointestinal disorders</b>			
<b>Abdominal pain</b>			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Aptyalism</b>			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Abdominal wall haematoma</b>			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Diarrhoea</b>			

subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon dysplasia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal perforation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hepatobiliary disorders</b>			
Hepatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Skin and subcutaneous tissue disorders</b>			
Drug reaction with eosinophilia and systemic symptoms			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Renal and urinary disorders</b>			
Acute kidney injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Endocrine disorders</b>			
Adrenal insufficiency			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Musculoskeletal and connective tissue disorders</b>			
Flank pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Infections and infestations</b>			
Bronchiolitis			

subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bronchitis</b>			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bronchitis viral</b>			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cellulitis</b>			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Influenza</b>			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Lower respiratory tract infection</b>			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Lower respiratory tract infection viral</b>			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Lung infection</b>			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Neutropenic sepsis</b>			

subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural infection bacterial			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal infection			

subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Vascular device infection</b>			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Metabolism and nutrition disorders</b>			
<b>Dehydration</b>			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hyponatraemia</b>			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

<b>Serious adverse events</b>	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420		
<b>Total subjects affected by serious adverse events</b>			
subjects affected / exposed	6 / 10 (60.00%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>			
<b>Basal cell carcinoma</b>			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Prostate cancer</b>			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Squamous cell carcinoma of skin</b>			

subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of lung			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Jugular vein thrombosis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	0 / 10 (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	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General physical health deterioration			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malaise			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Generalised oedema			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pain			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 10 (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 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Organising pneumonia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pleural effusion			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Pneumonitis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Alanine aminotransferase increased			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General physical condition abnormal			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Post procedural haemorrhage			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			

subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Cardiac failure</b>			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Myocardial infarction</b>			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Nervous system disorders</b>			
<b>Cerebral ischaemia</b>			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Syncope</b>			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Blood and lymphatic system disorders</b>			
<b>Anaemia</b>			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Cytopenia</b>			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Febrile neutropenia</b>			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Neutropenia</b>			

subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Pancytopenia</b>			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Thrombocytopenia</b>			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Gastrointestinal disorders</b>			
<b>Abdominal pain</b>			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Aptyalism</b>			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Abdominal wall haematoma</b>			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Diarrhoea</b>			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Colon dysplasia</b>			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Gastric haemorrhage</b>			

subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal perforation			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematemesis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small intestinal haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small intestinal obstruction			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Hepatitis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperbilirubinaemia			

subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Skin and subcutaneous tissue disorders</b>			
Drug reaction with eosinophilia and systemic symptoms			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Renal and urinary disorders</b>			
Acute kidney injury			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Endocrine disorders</b>			
Adrenal insufficiency			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Musculoskeletal and connective tissue disorders</b>			
Flank pain			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Infections and infestations</b>			
Bronchiolitis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchitis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchitis viral			

subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cellulitis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Influenza			
subjects affected / exposed	0 / 10 (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 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung infection			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neutropenic sepsis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Parainfluenzae virus infection			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pleural infection bacterial			

subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Pneumonia</b>			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Septic shock</b>			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Sepsis</b>			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Skin infection</b>			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Sinusitis</b>			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Streptococcal infection</b>			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Vascular device infection</b>			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Metabolism and nutrition disorders</b>			
Dehydration			

subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

<b>Non-serious adverse events</b>	Part 1 Arm A: DUR 1500 + LEN 20 + RIT 375	Part 1 Arm A: DUR 1500 + LEN 20	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 70
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)			
Cancer pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Tumour flare			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Haematoma			
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
Venous thrombosis limb			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aortic stenosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Embolism</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Deep vein thrombosis</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Axillary vein thrombosis</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Subclavian vein thrombosis</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Shock</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Embolism venous</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
<b>Venous thrombosis</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>General disorders and administration site conditions</b>			
<b>Chills</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
<b>Asthenia</b>			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
<b>Influenza like illness</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>General physical health deterioration</b>			

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)	3	3	1
Early satiety			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Mucosal inflammation			
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
Pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	1	1	2
Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gravitational oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Inflammation			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
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
Nodule			
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
Pneumatosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Temperature intolerance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Immunodeficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypogammaglobulinaemia			
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			
Benign prostatic hyperplasia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	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
Penile oedema 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)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 4 (0.00%) 0
Dyspnoea subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 4 (0.00%) 0
Epistaxis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Nasal congestion subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 4 (0.00%) 0
Laryngeal inflammation subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Hypoxia			

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
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Sinus disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Allergic cough			
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
Chronic obstructive pulmonary disease			
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%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1

Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Interstitial lung disease			
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
Pharyngeal erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	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
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Rales			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema			
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

Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Apathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Confusional state			
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%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiovascular somatic symptom disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	4
Disorientation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Panic attack			
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	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	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 alkaline phosphatase 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
Blood glucose 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	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Immunoglobulins decreased			
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%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Lipase increased			
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%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
White blood cell count decreased			

subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	5	0
Amylase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood calcium decreased			
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
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood urine present			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Heart rate irregular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Creatinine renal clearance increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count 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
Monocyte count increased			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Streptococcus test positive subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Urine output decreased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Weight increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 4 (25.00%) 3
Injury, poisoning and procedural complications			
Contusion subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Ligament sprain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Infusion related reaction subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1
Fall subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Overdose subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Wound subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Skin laceration subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 2	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Allergic transfusion reaction			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Humerus fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
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%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Neck injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Subdural haematoma			
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
Thermal burn			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Transfusion reaction			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Congenital, familial and genetic disorders			
Epidermolysis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Cardiac disorders			
Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Pericardial disease subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 4 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Tachycardia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Supraventricular tachycardia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Sinus bradycardia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Nervous system disorders			
Dysaesthesia 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	0 / 4 (0.00%) 0
Aphasia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Dysgeusia</b>			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
<b>Peripheral sensory neuropathy</b>			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
<b>Paraesthesia</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Migraine</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Headache</b>			
subjects affected / exposed	2 / 3 (66.67%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	3	1	2
<b>Tremor</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Amnesia</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Depressed level of consciousness</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Hypoaesthesia</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Lethargy</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Memory impairment</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Sciatica</b>			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Syncope			
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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Eosinophilia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Haemolytic anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	3
Neutropenia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	2 / 4 (50.00%)
occurrences (all)	4	3	4

Thrombocytopenia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 2	0 / 3 (0.00%) 0	1 / 4 (25.00%) 3
Pancytopenia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Immune thrombocytopenic purpura subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Bone marrow failure subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Increased tendency to bruise subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Ear and labyrinth disorders Tinnitus subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Hypoacusis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Ear pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Ear discomfort subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Eye disorders Blepharitis subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Retinopathy hypertensive			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Conjunctival haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctival oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Angle closure glaucoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eyelid disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Iritis			
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
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitreous haemorrhage			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Vitreous floaters subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Vitreous detachment subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Visual impairment subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
<b>Gastrointestinal disorders</b>			
Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Abdominal distension subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	1 / 3 (33.33%) 2	1 / 4 (25.00%) 1
Constipation subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 3	3 / 3 (100.00%) 7	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
Abdominal pain subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	1 / 4 (25.00%) 3
Dyspepsia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Dry mouth subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 4 (0.00%) 0

Dysphagia			
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
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Gingival pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
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
Nausea			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	1	1	2
Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Oral pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Abdominal hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal wall haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dental caries			
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
Haematemesis			
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
Lip dry			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oesophageal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lip haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Toothache subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Upper gastrointestinal haemorrhage subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
<b>Hepatobiliary disorders</b>			
<b>Hepatitis</b>			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
<b>Hepatocellular injury</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Hypertransaminasaemia</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Cholestasis</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Jaundice cholestatic</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Ocular icterus</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Skin and subcutaneous tissue disorders</b>			
<b>Dermatitis exfoliative generalised</b>			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
<b>Dermatitis acneiform</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Dry skin</b>			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	2	0	2
<b>Erythema</b>			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
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%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Skin fissures			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Skin lesion			
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
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
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
<b>Dermatitis contact</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Eczema asteatotic</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Onychoclasia</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Neurodermatitis</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Hyperkeratosis</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Eczema nummular</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Petechiae</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Pruritus generalised</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Psoriasis</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Purpura</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Rash generalised</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Rash macular</b>			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Rash pruritic subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Renal and urinary disorders			
Acute kidney injury subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Dysuria subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Haematuria subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Micturition urgency subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Renal failure subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	2 / 3 (66.67%) 2	1 / 4 (25.00%) 1
Cystitis haemorrhagic subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Pollakiuria subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Renal colic subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Renal impairment subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Ureterolithiasis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0

Urinary tract pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Urinary incontinence subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Endocrine disorders			
Hyperthyroidism subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Hypothyroidism subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Thyroiditis subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Back pain subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	1 / 3 (33.33%) 1	1 / 4 (25.00%) 3
Bone pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Groin pain subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 2	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Flank pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Intervertebral disc degeneration subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 4 (0.00%) 0
Muscle discomfort			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Muscular weakness			
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%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	3 / 3 (100.00%)	2 / 3 (66.67%)	0 / 4 (0.00%)
occurrences (all)	3	2	0
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Periarthritis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Arthritis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Limb mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint noise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc disorder			
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
Rotator cuff syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Synovial cyst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Cystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Folliculitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
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
Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Lip infection			
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
Metapneumovirus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lung 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			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Otitis externa			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinovirus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
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
Tonsillitis			
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	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear 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
Chronic sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bacterial sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Herpes ophthalmic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Enterocolitis infectious			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Pharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
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
Human herpesvirus 6 infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonia pseudomonal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stenotrophomonas sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pseudomonas infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Prostate infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	3
Dehydration			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 3 (33.33%)	2 / 3 (66.67%)	0 / 4 (0.00%)
occurrences (all)	1	3	0
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	5	0
Hypomagnesaemia			
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
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Hyperlactacidaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Polydipsia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	3
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tumour lysis syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

<b>Non-serious adverse events</b>	Part 1 Arm C: DUR 1500 + BEN 70	Part 1 Arm C: DUR 1500 + RIT 375	Part 1 Arm B: DUR 1500 + IBR 560
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	3 / 3 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tumour flare			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Venous thrombosis limb			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypotension			

subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Aortic stenosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Axillary vein thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Subclavian vein thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Shock			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Embolism venous			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Influenza like illness			

subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Early satiety			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Mucosal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Discomfort			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Face oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gravitational oedema			

subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Inflammation</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Gait disturbance</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Feeling hot</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Injection site bruising</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
<b>Localised oedema</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Nodule</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Peripheral swelling</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Pneumatosis</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Temperature intolerance</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
<b>Immune system disorders</b>			
<b>Drug hypersensitivity</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Immunodeficiency</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Hypogammaglobulinaemia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Reproductive system and breast disorders			
Benign prostatic hyperplasia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1
Penile oedema subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Vaginal haemorrhage subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 3 (33.33%) 1	1 / 4 (25.00%) 1
Dyspnoea subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 3 (33.33%) 1	2 / 4 (50.00%) 4
Epistaxis subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1
Nasal congestion subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1
Laryngeal inflammation			

subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
<b>Hypoxia</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Pleural effusion</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	3
<b>Productive cough</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
<b>Sinus congestion</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
<b>Sinus disorder</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Sinus pain</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
<b>Tachypnoea</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Allergic cough</b>			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
<b>Asthma</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Chronic obstructive pulmonary disease</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Dysphonia</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Hiccups			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Interstitial lung disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pharyngeal erythema			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Nasal obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Wheezing subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Psychiatric disorders			
Anxiety subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Apathy subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Confusional state subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Depression subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Insomnia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Cardiovascular somatic symptom disorder subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Disorientation subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Irritability subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Panic attack subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Aspartate aminotransferase increased			

subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Immunoglobulins decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Weight decreased			

subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood calcium decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood urine present			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Heart rate irregular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Creatinine renal clearance increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			

subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	3
Monocyte count increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Streptococcus test positive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Ligament sprain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Overdose			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin laceration			

subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Allergic transfusion reaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye contusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Humerus fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Neck injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Subdural haematoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Thermal burn			

subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Transfusion reaction subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Congenital, familial and genetic disorders Epidermolysis subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Cardiac disorders Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Pericardial disease subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	2 / 4 (50.00%) 2
Tachycardia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Supraventricular tachycardia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Sinus bradycardia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1
Nervous system disorders Dysaesthesia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Dizziness			

subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
<b>Aphasia</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Dysgeusia</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Peripheral sensory neuropathy</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Paraesthesia</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Migraine</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Headache</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
<b>Tremor</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Amnesia</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Depressed level of consciousness</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Hypoaesthesia</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Lethargy</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Memory impairment</b>			

subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 1 (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 / 1 (0.00%)	0 / 3 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	4
Eosinophilia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemolytic anaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	3
Pancytopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Immune thrombocytopenic purpura			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bone marrow failure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Increased tendency to bruise			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Eye disorders			

Blepharitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Retinopathy hypertensive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Conjunctival haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Conjunctival oedema			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Angle closure glaucoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Conjunctivitis allergic			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Eyelid disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Iritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Vision blurred			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitreous haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitreous detachment			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	2 / 4 (50.00%)
occurrences (all)	0	1	5
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	3 / 4 (75.00%)
occurrences (all)	0	1	3
Abdominal pain upper			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	3
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	2 / 4 (50.00%)
occurrences (all)	0	1	3
Dyspepsia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Dysphagia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Gingival pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	2 / 4 (50.00%)
occurrences (all)	0	1	2
Rectal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Oral pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stomatitis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal hernia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Anal fissure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal wall haematoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Ascites			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dental caries			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematemesis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oesophageal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Lip haematoma			

subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Proctalgia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Toothache subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Upper gastrointestinal haemorrhage subjects affected / exposed occurrences (all)	1 / 1 (100.00%) 1	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Hepatobiliary disorders Hepatitis subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Hepatocellular injury subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Hypertransaminasaemia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Cholestasis subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Jaundice cholestatic subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Ocular icterus subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Skin and subcutaneous tissue disorders Dermatitis exfoliative generalised subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Dermatitis acneiform			

subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Ecchymosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hyperhidrosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	4
Night sweats			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Rash			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	2 / 4 (50.00%)
occurrences (all)	0	1	4
Rash maculo-papular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Skin fissures			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	3
Urticaria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Alopecia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eczema asteatotic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Onychoclasia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Neurodermatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eczema nummular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus generalised			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Purpura			

subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Rash generalised subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Rash macular subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Rash pruritic subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
<b>Renal and urinary disorders</b>			
Acute kidney injury subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Dysuria subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Haematuria subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	1 / 4 (25.00%) 3
Micturition urgency subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Renal failure subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Cystitis haemorrhagic subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Pollakiuria subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Renal colic subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0

Renal impairment subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Ureterolithiasis subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Urinary tract pain subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Urinary incontinence subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Endocrine disorders Hyperthyroidism subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1
Hypothyroidism subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1
Thyroiditis subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	2 / 4 (50.00%) 4
Back pain subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Bone pain subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Groin pain subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Flank pain			

subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc degeneration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	3
Muscular weakness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Musculoskeletal discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pain in jaw			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Neck pain			

subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Periarthritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Arthritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle mass			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Limb mass			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint noise			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Rotator cuff syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Synovial cyst			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
subjects affected / exposed	0 / 1 (0.00%)	2 / 3 (66.67%)	1 / 4 (25.00%)
occurrences (all)	0	4	1

Cystitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Gastroenteritis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Laryngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Gastroenteritis viral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Lip infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Metapneumovirus infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lung infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Lower respiratory tract infection subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Oral candidiasis subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Otitis externa subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Paronychia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Pneumonia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1
Respiratory tract infection subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Oral fungal infection subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Sinusitis subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	2 / 4 (50.00%) 3
Rhinovirus infection subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Rhinitis subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1
Skin infection subjects affected / exposed occurrences (all)	1 / 1 (100.00%) 1	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Tonsillitis subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0

Tooth infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	2	4
Viral infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chronic sinusitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Bacterial sepsis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Herpes ophthalmic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Eye infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Hordeolum			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Enterocolitis infectious			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Human herpesvirus 6 infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonia pseudomonal			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stenotrophomonas sepsis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pseudomonas infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Prostate infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection viral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperlactacidaemia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Gout</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Polydipsia</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Hyponatraemia</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Hypoglycaemia</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Hypertriglyceridaemia</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
<b>Tumour lysis syndrome</b>			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

<b>Non-serious adverse events</b>	Part 1 Arm B: DUR 1500 + IBR 420	Part 1 Arm A: DUR 1500 + LEN 10 + RIT 375	Part 2, Arm D CLL/SLL: DUR 1500 mg
<b>Total subjects affected by non-serious adverse events</b>			
subjects affected / exposed	3 / 3 (100.00%)	8 / 8 (100.00%)	2 / 2 (100.00%)
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>			
<b>Cancer pain</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Tumour flare</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Vascular disorders</b>			
<b>Haematoma</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Hypertension</b>			

subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Venous thrombosis limb			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Aortic stenosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Axillary vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Subclavian vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Shock			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Embolism venous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chills			

subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Asthenia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	2 / 2 (100.00%)
occurrences (all)	1	0	2
Influenza like illness			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
General physical health deterioration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 3 (33.33%)	2 / 8 (25.00%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Early satiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	2 / 8 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 8 (25.00%)	1 / 2 (50.00%)
occurrences (all)	0	2	2
Discomfort			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gravitational oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumatosis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Temperature intolerance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			

Drug hypersensitivity subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Immunodeficiency subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Hypogammaglobulinaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Reproductive system and breast disorders			
Benign prostatic hyperplasia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Penile oedema subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Vaginal haemorrhage subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	1 / 8 (12.50%) 1	0 / 2 (0.00%) 0
Dyspnoea subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	3 / 8 (37.50%) 4	0 / 2 (0.00%) 0
Epistaxis subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Nasal congestion			

subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Laryngeal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Sinus congestion			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Sinus disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinus pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Tachypnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Allergic cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chronic obstructive pulmonary			

disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Interstitial lung disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pharyngeal erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Rales			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Apathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	2 / 3 (66.67%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiovascular somatic symptom disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Panic attack			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
<b>Investigations</b>			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	1 / 8 (12.50%) 1	0 / 2 (0.00%) 0
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1	0 / 2 (0.00%) 0
Blood bilirubin increased subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 2	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1	0 / 2 (0.00%) 0
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1	0 / 2 (0.00%) 0
Blood glucose increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1	0 / 2 (0.00%) 0
Blood creatinine increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Gamma-glutamyltransferase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1	0 / 2 (0.00%) 0
Immunoglobulins decreased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Lymphocyte count decreased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Lipase increased			

subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Platelet count decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Amylase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood calcium decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood urine present			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Heart rate irregular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Creatinine renal clearance increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Lymphocyte count increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Neutrophil count decreased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Monocyte count increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Streptococcus test positive subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Urine output decreased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Weight increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Injury, poisoning and procedural complications			
Contusion subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Ligament sprain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1	0 / 2 (0.00%) 0
Infusion related reaction subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	2 / 8 (25.00%) 3	0 / 2 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Overdose			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Allergic transfusion reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Humerus fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neck injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Subdural haematoma			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Tooth fracture subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Thermal burn subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Transfusion reaction subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Congenital, familial and genetic disorders			
Epidermolysis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1	0 / 2 (0.00%) 0
Cardiac disorders			
Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Pericardial disease subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Tachycardia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Supraventricular tachycardia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Sinus bradycardia			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
<b>Nervous system disorders</b>			
<b>Dysaesthesia</b>			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1	0 / 2 (0.00%) 0
<b>Dizziness</b>			
subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
<b>Aphasia</b>			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
<b>Dysgeusia</b>			
subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	1 / 8 (12.50%) 1	0 / 2 (0.00%) 0
<b>Peripheral sensory neuropathy</b>			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1	0 / 2 (0.00%) 0
<b>Paraesthesia</b>			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
<b>Migraine</b>			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
<b>Headache</b>			
subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
<b>Tremor</b>			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
<b>Amnesia</b>			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
<b>Depressed level of consciousness</b>			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0

Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 8 (37.50%)	2 / 2 (100.00%)
occurrences (all)	0	4	3
Eosinophilia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haemolytic anaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
<b>Leukopenia</b>			
subjects affected / exposed	0 / 3 (0.00%)	3 / 8 (37.50%)	0 / 2 (0.00%)
occurrences (all)	0	7	0
<b>Lymphopenia</b>			
subjects affected / exposed	0 / 3 (0.00%)	2 / 8 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
<b>Neutropenia</b>			
subjects affected / exposed	1 / 3 (33.33%)	4 / 8 (50.00%)	2 / 2 (100.00%)
occurrences (all)	1	9	5
<b>Thrombocytopenia</b>			
subjects affected / exposed	0 / 3 (0.00%)	2 / 8 (25.00%)	2 / 2 (100.00%)
occurrences (all)	0	2	6
<b>Pancytopenia</b>			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
<b>Immune thrombocytopenic purpura</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Bone marrow failure</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Increased tendency to bruise</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Ear and labyrinth disorders</b>			
<b>Tinnitus</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Hypoacusis</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Ear pain</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Ear discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Retinopathy hypertensive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	2
Cataract			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Conjunctival oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Angle closure glaucoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eyelid disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Iritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vitreous haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vitreous detachment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	3 / 3 (100.00%)	2 / 8 (25.00%)	0 / 2 (0.00%)
occurrences (all)	5	2	0
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	4 / 8 (50.00%)	0 / 2 (0.00%)
occurrences (all)	0	4	0

Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 8 (12.50%) 2	0 / 2 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1	0 / 2 (0.00%) 0
Dyspepsia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	1 / 2 (50.00%) 1
Dry mouth subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Dysphagia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Flatulence subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Gastrointestinal haemorrhage subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Gingival pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Haemorrhoids subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Mouth ulceration subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0

Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 3 (33.33%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Abdominal hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Abdominal wall haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dental caries			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Eructation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haematemesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0

Lip dry			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oesophageal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lip haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatocellular injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cholestasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Jaundice cholestatic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ocular icterus			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Skin and subcutaneous tissue disorders</b>			
<b>Dermatitis exfoliative generalised</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Dermatitis acneiform</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Dry skin</b>			
subjects affected / exposed	1 / 3 (33.33%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
<b>Erythema</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Ecchymosis</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Hyperhidrosis</b>			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
<b>Night sweats</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Pruritus</b>			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
<b>Rash</b>			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
<b>Rash maculo-papular</b>			
subjects affected / exposed	1 / 3 (33.33%)	2 / 8 (25.00%)	0 / 2 (0.00%)
occurrences (all)	1	8	0
<b>Skin fissures</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Skin lesion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eczema asteatotic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Onychoclasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neurodermatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eczema nummular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Pruritus generalised			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash generalised			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cystitis haemorrhagic			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Pollakiuria</b>			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
<b>Renal colic</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Renal impairment</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Ureterolithiasis</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Urinary tract pain</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Urinary incontinence</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Endocrine disorders</b>			
<b>Hyperthyroidism</b>			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
<b>Hypothyroidism</b>			
subjects affected / exposed	0 / 3 (0.00%)	2 / 8 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
<b>Thyroiditis</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Musculoskeletal and connective tissue disorders</b>			
<b>Arthralgia</b>			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
<b>Back pain</b>			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Bone pain</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Groin pain</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Flank pain</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Intervertebral disc degeneration</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Muscle discomfort</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Joint swelling</b>			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
<b>Muscle spasms</b>			
subjects affected / exposed	1 / 3 (33.33%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
<b>Muscular weakness</b>			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
<b>Musculoskeletal chest pain</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Musculoskeletal discomfort</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Musculoskeletal pain</b>			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
<b>Pain in jaw</b>			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Periarthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Arthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscle mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Limb mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Joint noise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Synovial cyst			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
<b>Infections and infestations</b>			
<b>Bronchiolitis</b>			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
<b>Bronchitis</b>			
subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
<b>Cystitis</b>			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 8 (12.50%) 2	0 / 2 (0.00%) 0
<b>Cytomegalovirus infection</b>			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
<b>Folliculitis</b>			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1	0 / 2 (0.00%) 0
<b>Gastroenteritis</b>			
subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
<b>Laryngitis</b>			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
<b>Influenza</b>			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1	0 / 2 (0.00%) 0
<b>Herpes zoster</b>			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
<b>Gastroenteritis viral</b>			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
<b>Lip infection</b>			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1	0 / 2 (0.00%) 0

Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Metapneumovirus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lung infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Otitis externa			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Rhinovirus infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0

Rhinitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 3 (33.33%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chronic sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bacterial sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Herpes virus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Herpes ophthalmic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Enterocolitis infectious			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Human herpesvirus 6 infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumonia pseudomonal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Stenotrophomonas sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Pseudomonas infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Prostate infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Urinary tract infection viral subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Metabolism and nutrition disorders			
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Dehydration subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Decreased appetite subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	2 / 8 (25.00%) 2	0 / 2 (0.00%) 0
Hyperuricaemia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Hyperkalaemia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Hypoalbuminaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Hypocalcaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0	1 / 2 (50.00%) 1
Hypokalaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1	0 / 2 (0.00%) 0
Hypomagnesaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Hypophosphataemia</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Hypercalcaemia</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Hyperlactacidaemia</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Gout</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Polydipsia</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Hyponatraemia</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Hypoglycaemia</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Hypertriglyceridaemia</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
<b>Tumour lysis syndrome</b>			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

<b>Non-serious adverse events</b>	Part 2, Arm D MCL: DUR 1500 mg	Part 2, Arm D DLBCL: DUR 1500 mg	Part 2 Arm D FL: DUR 1500
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	10 / 10 (100.00%)	5 / 5 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Cancer pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tumour flare			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis limb			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	2 / 5 (40.00%)
occurrences (all)	1	0	2
Aortic stenosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Axillary vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Subclavian vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Shock			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Embolism venous			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Asthenia			
subjects affected / exposed	3 / 5 (60.00%)	2 / 10 (20.00%)	1 / 5 (20.00%)
occurrences (all)	4	2	1
Influenza like illness			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
General physical health deterioration			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Fatigue			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Early satiety			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Malaise			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	2 / 5 (40.00%)
occurrences (all)	0	1	3
Pyrexia			
subjects affected / exposed	4 / 5 (80.00%)	6 / 10 (60.00%)	2 / 5 (40.00%)
occurrences (all)	5	8	3
Discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gravitational oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nodule			

subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Peripheral swelling subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Pneumatosis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Temperature intolerance subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
<b>Immune system disorders</b>			
Drug hypersensitivity subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Immunodeficiency subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1
Hypogammaglobulinaemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
<b>Reproductive system and breast disorders</b>			
Benign prostatic hyperplasia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Penile oedema subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1
Vaginal haemorrhage			

subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 5 (40.00%)	1 / 10 (10.00%)	2 / 5 (40.00%)
occurrences (all)	2	1	2
Dyspnoea			
subjects affected / exposed	0 / 5 (0.00%)	2 / 10 (20.00%)	3 / 5 (60.00%)
occurrences (all)	0	3	3
Epistaxis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Laryngeal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Pleural effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Productive cough			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Sinus congestion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinus disorder			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinus pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Allergic cough			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hiccups			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Interstitial lung disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pharyngeal erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Nasal obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Pulmonary oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Apathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Confusional state			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Depression			

subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Cardiovascular somatic symptom disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Irritability			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Panic attack			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Blood bilirubin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	2
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Immunoglobulins decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	3 / 5 (60.00%)	1 / 10 (10.00%)	1 / 5 (20.00%)
occurrences (all)	3	1	1
White blood cell count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood calcium decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Blood urine present			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Heart rate irregular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Creatinine renal clearance increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Monocyte count increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Streptococcus test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Weight increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Contusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	2 / 5 (40.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Overdose			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Wound			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Skin laceration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Allergic transfusion reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye contusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Humerus fracture			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Joint dislocation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Procedural pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neck injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Subdural haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Transfusion reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Epidermolysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Pericardial disease			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Supraventricular tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Sinus bradycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dysaesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 5 (20.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Aphasia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Dysgeusia			
subjects affected / exposed	2 / 5 (40.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	2	0	1
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Paraesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Headache			
subjects affected / exposed	1 / 5 (20.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Tremor			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Amnesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Depressed level of consciousness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Sciatica			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Somnolence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 5 (20.00%)	2 / 10 (20.00%)	1 / 5 (20.00%)
occurrences (all)	7	4	1
Eosinophilia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Febrile neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemolytic anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	3 / 5 (60.00%)	3 / 10 (30.00%)	0 / 5 (0.00%)
occurrences (all)	8	5	0
Thrombocytopenia			
subjects affected / exposed	3 / 5 (60.00%)	4 / 10 (40.00%)	1 / 5 (20.00%)
occurrences (all)	6	4	1
Pancytopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Immune thrombocytopenic purpura			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bone marrow failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Increased tendency to bruise			

subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
<b>Ear and labyrinth disorders</b>			
<b>Tinnitus</b>			
subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
<b>Hypoacusis</b>			
subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
<b>Ear pain</b>			
subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1
<b>Ear discomfort</b>			
subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
<b>Vertigo</b>			
subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	1 / 10 (10.00%) 1	0 / 5 (0.00%) 0
<b>Eye disorders</b>			
<b>Blepharitis</b>			
subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
<b>Retinopathy hypertensive</b>			
subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
<b>Dry eye</b>			
subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
<b>Conjunctival haemorrhage</b>			
subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
<b>Cataract</b>			
subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 10 (10.00%) 1	0 / 5 (0.00%) 0
<b>Conjunctival oedema</b>			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Angle closure glaucoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eyelid disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Iritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Vision blurred			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Vitreous haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Vitreous detachment			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

Abdominal discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	2 / 5 (40.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	3	0	1
Constipation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	2
Abdominal pain upper			
subjects affected / exposed	1 / 5 (20.00%)	1 / 10 (10.00%)	1 / 5 (20.00%)
occurrences (all)	1	1	1
Abdominal pain			
subjects affected / exposed	1 / 5 (20.00%)	1 / 10 (10.00%)	1 / 5 (20.00%)
occurrences (all)	2	1	1
Dyspepsia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Dry mouth			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Dysphagia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1

Gingival pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Mouth ulceration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 5 (60.00%)	1 / 10 (10.00%)	1 / 5 (20.00%)
occurrences (all)	4	1	1
Rectal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 5 (20.00%)	1 / 10 (10.00%)	1 / 5 (20.00%)
occurrences (all)	1	1	1
Abdominal hernia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal wall haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Dental caries			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haematemesis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Gastritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oesophageal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lip haematoma			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Proctalgia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hepatocellular injury			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
<b>Hypertransaminasaemia</b>			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
<b>Cholestasis</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
<b>Jaundice cholestatic</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
<b>Ocular icterus</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
<b>Skin and subcutaneous tissue disorders</b>			
<b>Dermatitis exfoliative generalised</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
<b>Dermatitis acneiform</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
<b>Dry skin</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
<b>Erythema</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
<b>Ecchymosis</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
<b>Hyperhidrosis</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
<b>Night sweats</b>			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Pruritus			
subjects affected / exposed	1 / 5 (20.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Rash			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	2 / 5 (40.00%)
occurrences (all)	0	1	2
Rash maculo-papular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eczema asteatotic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Onychoclasia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Neurodermatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eczema nummular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pruritus generalised			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Rash generalised			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Rash macular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysuria			

subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Haematuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cystitis haemorrhagic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Renal colic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Renal impairment			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Ureterolithiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0

Hypothyroidism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Thyroiditis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 5 (20.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Bone pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Groin pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Intervertebral disc degeneration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscle discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Periarthritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Arthritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscle mass			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Limb mass			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Joint noise			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Synovial cyst			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
<b>Infections and infestations</b>			
Bronchiolitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Folliculitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Laryngitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Influenza			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lip infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Metapneumovirus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Lung infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Otitis externa			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0

Respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Oral fungal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rhinovirus infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Viral infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Conjunctivitis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Chronic sinusitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bacterial sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Herpes virus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Herpes ophthalmic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Enterocolitis infectious			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Human herpesvirus 6 infection subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Pneumonia pseudomonal subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Stenotrophomonas sepsis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Sepsis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 10 (10.00%) 1	0 / 5 (0.00%) 0
Pseudomonas infection subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 10 (10.00%) 1	0 / 5 (0.00%) 0
Prostate infection subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Urinary tract infection viral subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
<b>Metabolism and nutrition disorders</b>			
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Dehydration subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Decreased appetite subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	2 / 10 (20.00%) 2	2 / 5 (40.00%) 2
Hyperuricaemia subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 3	2 / 10 (20.00%) 2	0 / 5 (0.00%) 0
Hyperkalaemia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hypocalcaemia			
subjects affected / exposed	2 / 5 (40.00%)	1 / 10 (10.00%)	1 / 5 (20.00%)
occurrences (all)	2	1	1
Hypokalaemia			
subjects affected / exposed	3 / 5 (60.00%)	2 / 10 (20.00%)	1 / 5 (20.00%)
occurrences (all)	3	2	3
Hypomagnesaemia			
subjects affected / exposed	2 / 5 (40.00%)	1 / 10 (10.00%)	1 / 5 (20.00%)
occurrences (all)	2	1	1
Hypophosphataemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hyperlactacidaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Gout			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hyponatraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hypoglycaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			

subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Tumour lysis syndrome subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0

<b>Non-serious adverse events</b>	Part 2 Arm C CLL/SLL: DUR 1500 + RIT 375 + BEN 70	Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70
Total subjects affected by non-serious adverse events subjects affected / exposed	5 / 5 (100.00%)	9 / 10 (90.00%)	10 / 10 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Tumour flare			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Venous thrombosis limb			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Aortic stenosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Deep vein thrombosis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Axillary vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Subclavian vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Shock			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Embolism venous			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Asthenia			
subjects affected / exposed	0 / 5 (0.00%)	3 / 10 (30.00%)	1 / 10 (10.00%)
occurrences (all)	0	3	1
Influenza like illness			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
General physical health deterioration			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	2 / 5 (40.00%)	3 / 10 (30.00%)	3 / 10 (30.00%)
occurrences (all)	2	4	3
Early satiety			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Mucosal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	2 / 10 (20.00%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Malaise			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	1 / 5 (20.00%)	4 / 10 (40.00%)	3 / 10 (30.00%)
occurrences (all)	1	5	3
Discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gravitational oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Feeling hot			

subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Injection site bruising subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Localised oedema subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 10 (10.00%) 1	0 / 10 (0.00%) 0
Nodule subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 10 (10.00%) 1	0 / 10 (0.00%) 0
Peripheral swelling subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	1 / 10 (10.00%) 1
Pneumatosis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Temperature intolerance subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Immune system disorders			
Drug hypersensitivity subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Immunodeficiency subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Hypogammaglobulinaemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	1 / 10 (10.00%) 1
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Reproductive system and breast disorders			

Benign prostatic hyperplasia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Penile oedema subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Vaginal haemorrhage subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	2 / 10 (20.00%) 3	4 / 10 (40.00%) 4
Dyspnoea subjects affected / exposed occurrences (all)	2 / 5 (40.00%) 3	2 / 10 (20.00%) 2	1 / 10 (10.00%) 1
Epistaxis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 10 (10.00%) 1	0 / 10 (0.00%) 0
Nasal congestion subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 10 (10.00%) 1	0 / 10 (0.00%) 0
Laryngeal inflammation subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Hypoxia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 10 (10.00%) 1	0 / 10 (0.00%) 0
Pleural effusion			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	1 / 10 (10.00%)
occurrences (all)	0	1	1
Sinus congestion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Sinus disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Sinus pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Allergic cough			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Interstitial lung disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pharyngeal erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nasal obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Upper-airway cough syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Anxiety			

subjects affected / exposed	1 / 5 (20.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Apathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	2 / 5 (40.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	2	1	0
Cardiovascular somatic symptom disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Panic attack			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	2
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	2
Blood bilirubin increased			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	2
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 5 (20.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Immunoglobulins decreased			
subjects affected / exposed	2 / 5 (40.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	3	0
Lipase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	3
Weight decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	1 / 10 (10.00%)
occurrences (all)	0	1	1
White blood cell count decreased			

subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Amylase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood calcium decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood urine present			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Heart rate irregular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Creatinine renal clearance increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Monocyte count increased			

subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Streptococcus test positive subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	1 / 10 (10.00%) 1
Urine output decreased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Weight increased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Injury, poisoning and procedural complications			
Contusion subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Ligament sprain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Infusion related reaction subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 10 (10.00%) 2	1 / 10 (10.00%) 1
Fall subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Overdose subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Wound subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Skin laceration subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 10 (10.00%) 1	0 / 10 (0.00%) 0
Allergic transfusion reaction			

subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Arthropod bite			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Eye contusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Humerus fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Neck injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Subdural haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Transfusion reaction			

subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Congenital, familial and genetic disorders			
Epidermolysis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Cardiac disorders			
Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 10 (10.00%) 1	1 / 10 (10.00%) 1
Pericardial disease subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Tachycardia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Supraventricular tachycardia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Sinus bradycardia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Nervous system disorders			
Dysaesthesia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Aphasia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	0 / 5 (0.00%)	2 / 10 (20.00%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Migraine			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 5 (20.00%)	1 / 10 (10.00%)	1 / 10 (10.00%)
occurrences (all)	1	2	1
Tremor			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Amnesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Depressed level of consciousness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Lethargy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Sciatica			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Syncope			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Somnolence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 5 (20.00%)	5 / 10 (50.00%)	1 / 10 (10.00%)
occurrences (all)	9	6	1
Eosinophilia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Haemolytic anaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Leukopenia			
subjects affected / exposed	0 / 5 (0.00%)	2 / 10 (20.00%)	1 / 10 (10.00%)
occurrences (all)	0	4	1
Lymphopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	1 / 5 (20.00%)	3 / 10 (30.00%)	6 / 10 (60.00%)
occurrences (all)	1	5	7

Thrombocytopenia subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	6 / 10 (60.00%) 10	2 / 10 (20.00%) 2
Pancytopenia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Immune thrombocytopenic purpura subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Bone marrow failure subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Increased tendency to bruise subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Ear and labyrinth disorders Tinnitus subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Hypoacusis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Ear pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Ear discomfort subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Eye disorders Blepharitis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Retinopathy hypertensive			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	1 / 5 (20.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Conjunctival haemorrhage			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Cataract			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Conjunctival oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Angle closure glaucoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Eyelid disorder			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Eyelid ptosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Iritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Vitreous haemorrhage			

subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	1 / 10 (10.00%) 1
Vitreous floaters subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Vitreous detachment subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	1 / 10 (10.00%) 1
Visual impairment subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
<b>Gastrointestinal disorders</b>			
Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Abdominal distension subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 2	1 / 10 (10.00%) 2	2 / 10 (20.00%) 3
Constipation subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	1 / 10 (10.00%) 1	3 / 10 (30.00%) 3
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	2 / 5 (40.00%) 2	1 / 10 (10.00%) 1	0 / 10 (0.00%) 0
Dyspepsia subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Dry mouth subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 10 (10.00%) 1	0 / 10 (0.00%) 0

Dysphagia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Gingival pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 5 (40.00%)	3 / 10 (30.00%)	3 / 10 (30.00%)
occurrences (all)	2	3	3
Rectal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 5 (0.00%)	2 / 10 (20.00%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Stomatitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	0 / 5 (0.00%)	2 / 10 (20.00%)	1 / 10 (10.00%)
occurrences (all)	0	4	2

Abdominal hernia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Abdominal wall haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dental caries			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Haematemesis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Oesophageal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Lip haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Toothache subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 10 (10.00%) 1	0 / 10 (0.00%) 0
Upper gastrointestinal haemorrhage subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Hepatobiliary disorders			
Hepatitis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Hepatocellular injury subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Hypertransaminasaemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Cholestasis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Jaundice cholestatic subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Ocular icterus subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Skin and subcutaneous tissue disorders			
Dermatitis exfoliative generalised subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	1 / 10 (10.00%) 1
Dermatitis acneiform subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Dry skin subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Erythema			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Night sweats			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	1 / 5 (20.00%)	2 / 10 (20.00%)	1 / 10 (10.00%)
occurrences (all)	1	2	1
Rash			
subjects affected / exposed	1 / 5 (20.00%)	2 / 10 (20.00%)	0 / 10 (0.00%)
occurrences (all)	2	2	0
Rash maculo-papular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dermatitis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	2
Eczema asteatotic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Onychoclasia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Neurodermatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Hyperkeratosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Eczema nummular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Petechiae			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pruritus generalised			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rash generalised			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rash macular			

subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Rash pruritic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Haematuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Cystitis haemorrhagic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Renal colic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Renal impairment			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Ureterolithiasis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0

Urinary tract pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Urinary incontinence subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	1 / 10 (10.00%) 1
Endocrine disorders			
Hyperthyroidism subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Hypothyroidism subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Thyroiditis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Back pain subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 2	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Bone pain subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Groin pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Flank pain subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 10 (0.00%) 0	1 / 10 (10.00%) 1
Intervertebral disc degeneration subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Muscle discomfort			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Pain in jaw			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Periarthritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Arthritis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Muscle mass			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Limb mass			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Joint noise			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Synovial cyst			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Bronchitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	2 / 10 (20.00%)
occurrences (all)	0	1	2
Cystitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Folliculitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Laryngitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 5 (0.00%)	2 / 10 (20.00%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Gastroenteritis viral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Lip infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Metapneumovirus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Lung infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	2

Otitis externa			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Rhinovirus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
Tonsillitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	2 / 10 (20.00%)
occurrences (all)	0	0	2

Urinary tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Chronic sinusitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Bacterial sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Herpes ophthalmic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Hordeolum			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Enterocolitis infectious			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1

Pharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	1 / 5 (20.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Otitis media			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Human herpesvirus 6 infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pneumonia pseudomonal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Stenotrophomonas sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pseudomonas infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Prostate infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection viral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	1 / 10 (10.00%)
occurrences (all)	0	1	2
Dehydration			

subjects affected / exposed	2 / 5 (40.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Decreased appetite			
subjects affected / exposed	1 / 5 (20.00%)	3 / 10 (30.00%)	2 / 10 (20.00%)
occurrences (all)	1	3	2
Hyperuricaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Hypomagnesaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hyperlactacidaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Polydipsia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Tumour lysis syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1

<b>Non-serious adverse events</b>	Part 2 Arm B MCL: DUR 1500 + IBR 560	Part 2, Arm D HL: DUR 1500 mg	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 10 (100.00%)	5 / 5 (100.00%)	5 / 5 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tumour flare			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Venous thrombosis limb			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypotension			

subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	1 / 5 (20.00%) 2	0 / 5 (0.00%) 0
Aortic stenosis subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Embolism subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Deep vein thrombosis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Axillary vein thrombosis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Subclavian vein thrombosis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Shock subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Embolism venous subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Venous thrombosis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
General disorders and administration site conditions			
Chills subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Asthenia subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 2	2 / 5 (40.00%) 3	0 / 5 (0.00%) 0
Influenza like illness			

subjects affected / exposed	0 / 10 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
General physical health deterioration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 10 (20.00%)	0 / 5 (0.00%)	2 / 5 (40.00%)
occurrences (all)	2	0	2
Early satiety			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Pain			
subjects affected / exposed	0 / 10 (0.00%)	2 / 5 (40.00%)	0 / 5 (0.00%)
occurrences (all)	0	3	0
Oedema peripheral			
subjects affected / exposed	1 / 10 (10.00%)	2 / 5 (40.00%)	1 / 5 (20.00%)
occurrences (all)	1	2	1
Pyrexia			
subjects affected / exposed	2 / 10 (20.00%)	2 / 5 (40.00%)	3 / 5 (60.00%)
occurrences (all)	3	7	3
Discomfort			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Gravitational oedema			

subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Inflammation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Feeling hot			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumatosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Temperature intolerance			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Immunodeficiency			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Hypogammaglobulinaemia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Reproductive system and breast disorders			
Benign prostatic hyperplasia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Penile oedema subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Vaginal haemorrhage subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	1 / 5 (20.00%) 1	2 / 5 (40.00%) 2
Dyspnoea subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1	0 / 5 (0.00%) 0
Epistaxis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Nasal congestion subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	1 / 5 (20.00%) 1
Oropharyngeal pain subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Laryngeal inflammation			

subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Pleural effusion			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	2 / 5 (40.00%)
occurrences (all)	1	0	2
Productive cough			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinus disorder			
subjects affected / exposed	0 / 10 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Sinus pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Allergic cough			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Hiccups			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Interstitial lung disease			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Pleuritic pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pharyngeal erythema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasal obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0

Wheezing subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Psychiatric disorders			
Anxiety subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Apathy subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Confusional state subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Depression subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 2	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Insomnia subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	2 / 5 (40.00%) 2	0 / 5 (0.00%) 0
Cardiovascular somatic symptom disorder subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Disorientation subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Irritability subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Panic attack subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1	0 / 5 (0.00%) 0
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1	0 / 5 (0.00%) 0
Aspartate aminotransferase increased			

subjects affected / exposed	1 / 10 (10.00%)	1 / 5 (20.00%)	1 / 5 (20.00%)
occurrences (all)	1	1	1
Blood bilirubin increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 10 (10.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 10 (10.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Immunoglobulins decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Weight decreased			

subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
White blood cell count decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Blood calcium decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Blood urine present			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Heart rate irregular			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Creatinine renal clearance increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Lymphocyte count increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Neutrophil count decreased			

subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Monocyte count increased subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Streptococcus test positive subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Urine output decreased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Weight increased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Injury, poisoning and procedural complications			
Contusion subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 2	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Ligament sprain subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Infusion related reaction subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	1 / 5 (20.00%) 1
Fall subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Overdose subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Wound subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Skin laceration			

subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Allergic transfusion reaction			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Arthropod bite			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye contusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Humerus fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neck injury			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Limb injury			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Joint injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Subdural haematoma			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Tooth fracture			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Thermal burn			

subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Transfusion reaction subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Congenital, familial and genetic disorders			
Epidermolysis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Cardiac disorders			
Atrial fibrillation subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Pericardial disease subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Tachycardia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Supraventricular tachycardia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Sinus bradycardia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Nervous system disorders			
Dysaesthesia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Dizziness			

subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	2
<b>Aphasia</b>			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
<b>Dysgeusia</b>			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
<b>Peripheral sensory neuropathy</b>			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
<b>Paraesthesia</b>			
subjects affected / exposed	1 / 10 (10.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
<b>Migraine</b>			
subjects affected / exposed	0 / 10 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
<b>Headache</b>			
subjects affected / exposed	1 / 10 (10.00%)	2 / 5 (40.00%)	0 / 5 (0.00%)
occurrences (all)	1	2	0
<b>Tremor</b>			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
<b>Amnesia</b>			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
<b>Depressed level of consciousness</b>			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
<b>Hypoaesthesia</b>			
subjects affected / exposed	0 / 10 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
<b>Lethargy</b>			
subjects affected / exposed	1 / 10 (10.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
<b>Memory impairment</b>			

subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
<b>Blood and lymphatic system disorders</b>			
Anaemia			
subjects affected / exposed	3 / 10 (30.00%)	2 / 5 (40.00%)	3 / 5 (60.00%)
occurrences (all)	4	2	4
Eosinophilia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemolytic anaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	2 / 10 (20.00%)	0 / 5 (0.00%)	2 / 5 (40.00%)
occurrences (all)	3	0	4
Lymphopenia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	2 / 5 (40.00%)
occurrences (all)	1	0	3

Neutropenia			
subjects affected / exposed	3 / 10 (30.00%)	1 / 5 (20.00%)	1 / 5 (20.00%)
occurrences (all)	6	1	3
Thrombocytopenia			
subjects affected / exposed	3 / 10 (30.00%)	1 / 5 (20.00%)	2 / 5 (40.00%)
occurrences (all)	4	2	3
Pancytopenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Immune thrombocytopenic purpura			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bone marrow failure			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Increased tendency to bruise			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 10 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hypoacusis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Ear pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Ear discomfort			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Eye disorders			

Blepharitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Retinopathy hypertensive			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Conjunctival haemorrhage			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Cataract			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Conjunctival oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Angle closure glaucoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eyelid disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Iritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Vision blurred subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Vitreous haemorrhage subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Vitreous floaters subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Vitreous detachment subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Visual impairment subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Gastrointestinal disorders			
Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Abdominal distension subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	5 / 10 (50.00%) 6	3 / 5 (60.00%) 3	1 / 5 (20.00%) 2
Constipation subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 2	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	1 / 5 (20.00%) 1	2 / 5 (40.00%) 2
Dyspepsia			

subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Dry mouth			
subjects affected / exposed	1 / 10 (10.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Dysphagia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 10 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 10 (20.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Gingival pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	2 / 10 (20.00%)	1 / 5 (20.00%)	2 / 5 (40.00%)
occurrences (all)	2	1	2
Rectal haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Stomatitis			

subjects affected / exposed	2 / 10 (20.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	2	1	0
Vomiting			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Abdominal hernia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal wall haematoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Dental caries			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haematemesis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oesophageal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lip haematoma			

subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Proctalgia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Toothache subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 2	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Upper gastrointestinal haemorrhage subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Hepatobiliary disorders Hepatitis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Hepatocellular injury subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Hypertransaminasaemia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Cholestasis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Jaundice cholestatic subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	1 / 5 (20.00%) 1
Ocular icterus subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	1 / 5 (20.00%) 1
Skin and subcutaneous tissue disorders Dermatitis exfoliative generalised subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Dermatitis acneiform			

subjects affected / exposed	2 / 10 (20.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Dry skin			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Erythema			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Ecchymosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	0 / 10 (0.00%)	1 / 5 (20.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Rash			
subjects affected / exposed	4 / 10 (40.00%)	2 / 5 (40.00%)	0 / 5 (0.00%)
occurrences (all)	4	2	0
Rash maculo-papular			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Skin fissures			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	1 / 10 (10.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Urticaria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Alopecia			

subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Dermatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eczema asteatotic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Onychoclasia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neurodermatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eczema nummular			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Pruritus generalised			
subjects affected / exposed	0 / 10 (0.00%)	1 / 5 (20.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Psoriasis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Purpura			

subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Rash generalised subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Rash macular subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	1 / 5 (20.00%) 1	0 / 5 (0.00%) 0
Rash pruritic subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
<b>Renal and urinary disorders</b>			
Acute kidney injury subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Dysuria subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Haematuria subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 2	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Micturition urgency subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Renal failure subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Cystitis haemorrhagic subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Pollakiuria subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1	0 / 5 (0.00%) 0
Renal colic subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0

Renal impairment subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Ureterolithiasis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Urinary tract pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Urinary incontinence subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Endocrine disorders Hyperthyroidism subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Hypothyroidism subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Thyroiditis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 2	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Back pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	2 / 5 (40.00%) 2	1 / 5 (20.00%) 1
Bone pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1	0 / 5 (0.00%) 0
Groin pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Flank pain			

subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Intervertebral disc degeneration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscle discomfort			
subjects affected / exposed	0 / 10 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Joint swelling			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	3 / 10 (30.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	3	0	0
Muscular weakness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 10 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Pain in jaw			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 10 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neck pain			

subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Periarthritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Arthritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscle mass			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Limb mass			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Joint noise			
subjects affected / exposed	0 / 10 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Intervertebral disc disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Synovial cyst			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0

Cystitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lip infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Metapneumovirus infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lung infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Lower respiratory tract infection subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 2	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Oral candidiasis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Otitis externa subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Paronychia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Pneumonia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Respiratory tract infection subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Oral fungal infection subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Sinusitis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Rhinovirus infection subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	1 / 5 (20.00%) 1
Rhinitis subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Skin infection subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Tonsillitis subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	1 / 5 (20.00%) 1	0 / 5 (0.00%) 0

Tooth infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 10 (10.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	1	2	0
Urinary tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 10 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Ear infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chronic sinusitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bacterial sepsis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Herpes simplex			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Herpes ophthalmic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Hordeolum			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Enterocolitis infectious			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Human herpesvirus 6 infection			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Pneumonia pseudomonal			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Stenotrophomonas sepsis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Sepsis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Pseudomonas infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Prostate infection			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection viral			
subjects affected / exposed	1 / 10 (10.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0

Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 10 (10.00%)	2 / 5 (40.00%)	1 / 5 (20.00%)
occurrences (all)	1	3	1
Hyperuricaemia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Hyperkalaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Hypocalcaemia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Hypokalaemia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	4	1	0
Hypomagnesaemia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Hypophosphataemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hypercalcaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperlactacidaemia			

subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Gout subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Polydipsia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Hyponatraemia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Hypoglycaemia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Hypertriglyceridaemia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Tumour lysis syndrome subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0

<b>Non-serious adverse events</b>	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420		
Total subjects affected by non-serious adverse events subjects affected / exposed	10 / 10 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Cancer pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Tumour flare subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Vascular disorders Haematoma subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 2		
Hypertension			

subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Venous thrombosis limb subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Hypotension subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Aortic stenosis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Embolism subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Deep vein thrombosis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Axillary vein thrombosis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Subclavian vein thrombosis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Shock subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Embolism venous subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Venous thrombosis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
General disorders and administration site conditions Chills			

subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Asthenia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Influenza like illness			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
General physical health deterioration			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	3		
Early satiety			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Non-cardiac chest pain			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Mucosal inflammation			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Malaise			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Pain			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	2		
Oedema peripheral			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Pyrexia			
subjects affected / exposed	3 / 10 (30.00%)		
occurrences (all)	8		
Discomfort			

subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Face oedema			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Gravitational oedema			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Inflammation			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Gait disturbance			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Feeling hot			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Injection site bruising			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Localised oedema			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Nodule			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Peripheral swelling			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Pneumatosis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Temperature intolerance			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Immune system disorders			

Drug hypersensitivity subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Immunodeficiency subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Hypogammaglobulinaemia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Seasonal allergy subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Reproductive system and breast disorders			
Benign prostatic hyperplasia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Pelvic pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Penile oedema subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Vaginal haemorrhage subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	3 / 10 (30.00%) 5		
Dyspnoea subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Epistaxis subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 2		
Nasal congestion			

subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Oropharyngeal pain			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Laryngeal inflammation			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Hypoxia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Pleural effusion			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Productive cough			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Sinus congestion			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Sinus disorder			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Sinus pain			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Tachypnoea			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Allergic cough			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Asthma			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Chronic obstructive pulmonary			

disease			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Dysphonia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Hiccups			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Dyspnoea exertional			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Interstitial lung disease			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Pleuritic pain			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Pharyngeal erythema			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Nasal obstruction			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Nasal dryness			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Pneumonia aspiration			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Upper-airway cough syndrome			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		

Rales			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Pulmonary oedema			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Wheezing			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Apathy			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Confusional state			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Depression			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Insomnia			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Cardiovascular somatic symptom disorder			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Disorientation			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Irritability			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Panic attack			

subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
<b>Investigations</b>			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Blood bilirubin increased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Blood glucose increased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Blood creatinine increased subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 2		
Gamma-glutamyltransferase increased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Immunoglobulins decreased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Lymphocyte count decreased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Lipase increased			

subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Platelet count decreased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Weight decreased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Amylase increased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Blood calcium decreased subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Blood uric acid increased subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Blood lactate dehydrogenase increased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Blood urine present subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Heart rate irregular subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Creatinine renal clearance increased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
International normalised ratio increased			

subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Lymphocyte count increased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Neutrophil count decreased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Monocyte count increased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Streptococcus test positive subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Urine output decreased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Weight increased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Injury, poisoning and procedural complications			
Contusion subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 2		
Ligament sprain subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Infusion related reaction subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Fall subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 2		
Overdose			

subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Wound			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Skin laceration			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Allergic transfusion reaction			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Arthropod bite			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	2		
Eye contusion			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Humerus fracture			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Joint dislocation			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Procedural pain			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Neck injury			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Limb injury			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Joint injury			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Subdural haematoma			

subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Tooth fracture subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Thermal burn subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Transfusion reaction subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
<b>Congenital, familial and genetic disorders</b>			
Epidermolysis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
<b>Cardiac disorders</b>			
Atrial fibrillation subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 3		
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Pericardial disease subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Palpitations subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 2		
Tachycardia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Supraventricular tachycardia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Sinus bradycardia			

subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
<b>Nervous system disorders</b>			
<b>Dysaesthesia</b>			
subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
<b>Dizziness</b>			
subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
<b>Aphasia</b>			
subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
<b>Dysgeusia</b>			
subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
<b>Peripheral sensory neuropathy</b>			
subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
<b>Paraesthesia</b>			
subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
<b>Migraine</b>			
subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
<b>Headache</b>			
subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
<b>Tremor</b>			
subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
<b>Amnesia</b>			
subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
<b>Depressed level of consciousness</b>			
subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		

Hypoaesthesia			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Lethargy			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Memory impairment			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Sciatica			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Sensory disturbance			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Taste disorder			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Syncope			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Somnolence			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Eosinophilia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Febrile neutropenia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Haemolytic anaemia			

subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Leukopenia subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Lymphopenia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Neutropenia subjects affected / exposed occurrences (all)	4 / 10 (40.00%) 14		
Thrombocytopenia subjects affected / exposed occurrences (all)	3 / 10 (30.00%) 4		
Pancytopenia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Immune thrombocytopenic purpura subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Bone marrow failure subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Increased tendency to bruise subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Ear and labyrinth disorders			
Tinnitus subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Hypoacusis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Ear pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		

Ear discomfort			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Vertigo			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Retinopathy hypertensive			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Dry eye			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Conjunctival haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Cataract			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Conjunctival oedema			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Angle closure glaucoma			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Conjunctivitis allergic			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Eyelid disorder			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Eyelid ptosis			

subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Iritis subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Periorbital oedema subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Vision blurred subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Vitreous haemorrhage subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Vitreous floaters subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Vitreous detachment subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Visual impairment subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Gastrointestinal disorders			
Abdominal discomfort subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Abdominal distension subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Diarrhoea subjects affected / exposed occurrences (all)	5 / 10 (50.00%) 11		
Constipation subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		

Abdominal pain upper subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 2		
Abdominal pain subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 2		
Dyspepsia subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 2		
Dry mouth subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Dysphagia subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 2		
Flatulence subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Gastrointestinal haemorrhage subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Gingival pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Haemorrhoids subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Mouth ulceration subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Nausea subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		

Rectal haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Oral pain			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Stomatitis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Abdominal hernia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Anal fissure			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Abdominal wall haematoma			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Ascites			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Dental caries			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Eructation			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Haematemesis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Gastritis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		

Lip dry			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Oesophageal pain			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Lip haematoma			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Proctalgia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Toothache			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Hepatobiliary disorders			
Hepatitis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Hepatocellular injury			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	3		
Hypertransaminaemia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Cholestasis			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Jaundice cholestatic			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Ocular icterus			

subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
<b>Skin and subcutaneous tissue disorders</b>			
Dermatitis exfoliative generalised subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Dermatitis acneiform subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Dry skin subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Erythema subjects affected / exposed occurrences (all)	3 / 10 (30.00%) 3		
Ecchymosis subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Hyperhidrosis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Night sweats subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Pruritus subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Rash subjects affected / exposed occurrences (all)	4 / 10 (40.00%) 4		
Rash maculo-papular subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Skin fissures subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		

Skin lesion			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Urticaria			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Alopecia			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Decubitus ulcer			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Dermatitis			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Dermatitis contact			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Eczema asteatotic			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Onychoclasia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Neurodermatitis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Hyperkeratosis			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Eczema nummular			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Petechiae			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		

Pruritus generalised			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Psoriasis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Purpura			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Rash generalised			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Rash macular			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Rash pruritic			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Dysuria			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	2		
Haematuria			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Micturition urgency			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Renal failure			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Cystitis haemorrhagic			

subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Pollakiuria subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Renal colic subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Renal impairment subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Ureterolithiasis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Urinary tract pain subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Urinary incontinence subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Endocrine disorders Hyperthyroidism subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Hypothyroidism subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Thyroiditis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	3 / 10 (30.00%) 5		
Back pain			

subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Bone pain			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Groin pain			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Flank pain			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Intervertebral disc degeneration			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Muscle discomfort			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Joint swelling			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Muscle spasms			
subjects affected / exposed	3 / 10 (30.00%)		
occurrences (all)	3		
Muscular weakness			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Musculoskeletal chest pain			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Musculoskeletal discomfort			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Musculoskeletal pain			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Pain in jaw			

subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Myalgia			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	3		
Neck pain			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Periarthritis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Arthritis			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	2		
Muscle mass			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Limb mass			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Joint noise			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Intervertebral disc disorder			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Musculoskeletal stiffness			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Rotator cuff syndrome			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Synovial cyst			

subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
<b>Infections and infestations</b>			
<b>Bronchiolitis</b>			
subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
<b>Bronchitis</b>			
subjects affected / exposed occurrences (all)	3 / 10 (30.00%) 6		
<b>Cystitis</b>			
subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 2		
<b>Cytomegalovirus infection</b>			
subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
<b>Folliculitis</b>			
subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
<b>Gastroenteritis</b>			
subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
<b>Laryngitis</b>			
subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
<b>Influenza</b>			
subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
<b>Herpes zoster</b>			
subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
<b>Gastroenteritis viral</b>			
subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
<b>Lip infection</b>			
subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		

Nasopharyngitis			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	2		
Metapneumovirus infection			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Lung infection			
subjects affected / exposed	3 / 10 (30.00%)		
occurrences (all)	4		
Lower respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Oral candidiasis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Otitis externa			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	2		
Paronychia			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	3		
Pneumonia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Respiratory tract infection			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	4		
Oral fungal infection			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	2		
Sinusitis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Rhinovirus infection			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		

Rhinitis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Skin infection			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Tonsillitis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Tooth infection			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Urinary tract infection			
subjects affected / exposed	3 / 10 (30.00%)		
occurrences (all)	3		
Viral infection			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Ear infection			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Conjunctivitis			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Chronic sinusitis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Bacterial sepsis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Herpes simplex			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		

Herpes virus infection			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Herpes ophthalmic			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Eye infection			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Hordeolum			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Enterocolitis infectious			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Pharyngitis			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Otitis media acute			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Otitis media			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Human herpesvirus 6 infection			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Pneumonia pseudomonal			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Stenotrophomonas sepsis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Sepsis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		

Pseudomonas infection subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Prostate infection subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Urinary tract infection viral subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Metabolism and nutrition disorders			
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Dehydration subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Decreased appetite subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Hyperuricaemia subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Hyperkalaemia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Hypoalbuminaemia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Hypocalcaemia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Hypokalaemia subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Hypomagnesaemia			

subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Hypophosphataemia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Hypercalcaemia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Hyperlactacidaemia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Gout			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	4		
Polydipsia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Hyponatraemia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Hypoglycaemia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Hypertriglyceridaemia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Tumour lysis syndrome			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 May 2017	Addition of 2 new dose levels (ie, dose levels -2 and -3) to the Arm A dose finding part
14 December 2017	Discontinuation of Arm A to the enrollment of new participants
12 September 2019	Discontinuation of Follow-up Period, assessments and data collection
22 April 2020	Participants will move to a tablet formulation when the capsule formulation is no longer commercially available. For participants continuing on ibrutinib, scheduled clinic visits will be done according to standard of care per investigator's discretion.

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

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

Study placed on full clinical hold by US FDA on 05Sep2017. Study closed for further enrollment and subjects discontinued from all treatments. Subjects followed for SPMs for 5 years after last subject was enrolled per protocol

Notes: