Clinical trial results:
An Open-Label, Phase I/II, Dose-Escalation Study Evaluating the Safety and Tolerability of GDC-0032 in Patients with Locally Advanced or Metastatic Solid Tumors or Non-Hodgkin's Lymphoma and in Combination with Endocrine Therapy in Patients with Locally Advanced or Metastatic Hormone Receptor-Positive Breast Cancer

Summary

EudraCT number	2012-002042-21
Trial protocol	FR
Global end of trial date	25 June 2021

Results information

Result version number	v1 (current)
This version publication date	10 July 2022
First version publication date	10 July 2022

Trial information

Trial identification

Sponsor protocol code	PMT4979g

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01296555
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	F. Hoffmann-La Roche AG
Sponsor organisation address	Grenzacherstrasse 124, Basel, Switzerland, CH-4070
Public contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, +41 616878333, global.trial_information@roche.com
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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	25 June 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	25 June 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to assess the clinical efficacy of the combination of GDC-0032 and fulvestrant, as measured by the clinical benefit rate and objective response rate, in all participants and participants with PIK3CA-mutated breast cancer.

Protection of trial subjects:

All participants (or their parents or guardians) were required to read and sign an Informed Consent Form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 March 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 28
Country: Number of subjects enrolled	Spain: 136
Country: Number of subjects enrolled	France: 18
Country: Number of subjects enrolled	United States: 492
Worldwide total number of subjects	674
EEA total number of subjects	154

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)	432
From 65 to 84 years	232
85 years and over	10

Subject disposition

Recruitment

Recruitment details:

Participants took part in this study at 30 centers in Canada, France, Spain, and United States from 16 March 2011 to 25 June 2021.

Pre-assignment

Screening details:

Phase I: locally advanced or metastatic solid malignancy or NHL; post-menopausal locally advanced or metastatic hormone receptor-positive breast cancer (BC) +/- HER2-negative; NHL and DLBCL regardless of PIK3CA mutation; PIK3CA-mutant tumors. Phase II: post-menopausal locally advanced or metastatic HER2-negative, hormone receptor-positive BC.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Phase I, Stage 1: GDC-0032 3 milligrams (mg) once daily (QD)

Arm description:

Participants received GDC-0032 3 mg capsules, orally, once on Day 1 and then QD on Days 8 to 35 of Cycle 1 (Cycle 1 duration=35 days) and in subsequent 28-day cycles until disease progression.

Arm type	Experimental
Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Participants received taselisib 3 mg capsules, orally, once on Day 1 and then QD on Days 8 to 35 of Cycle 1 (Cycle 1 duration=35 days) and in subsequent 28-day cycles.

Arm title	Phase I, Stage 1: GDC-0032 5 mg QD

Arm description:

Participants received GDC-0032 5 mg capsules, orally, once on Day 1 and then QD on Days 8 to 35 of Cycle 1 (Cycle 1 duration=35 days) and in subsequent 28-day cycles until disease progression.

Arm type	Experimental
Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Participants received GDC-0032 5 mg capsules, orally, once on Day 1 and then QD on Days 8 to 35 of Cycle 1 (Cycle 1 duration=35 days) and in subsequent 28-day cycles.

Arm title	Phase I, Stage 1: GDC-0032 8 mg QD

Arm description:

Participants received GDC-0032 8 mg capsules, orally, once on Day 1 and then QD on Days 8 to 35 of Cycle 1 (Cycle 1 duration=35 days) and in subsequent 28-day cycles until disease progression.

Arm type	Experimental

Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Participants received GDC-0032 8 mg capsules, orally, once on Day 1 and then QD on Days 8 to 35 of Cycle 1 (Cycle 1 duration=35 days) and in subsequent 28-day cycles.

Arm title	Phase I, Stage 1: GDC-0032 12 mg QD

Arm description:

Participants received GDC-0032 12 mg capsules, orally, once on Day 1 and then QD on Days 8 to 35 of Cycle 1 (Cycle 1 duration=35 days) and in subsequent 28-day cycles until disease progression.

Arm type	Experimental
Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Participants received GDC-0032 12 mg capsules, orally, once on Day 1 and then QD on Days 8 to 35 of Cycle 1 (Cycle 1 duration=35 days) and in subsequent 28-day cycles.

Arm title	Phase I, Stage 1: GDC-0032 16 mg QD

Arm description:

Participants received GDC-0032 16 mg capsules, orally, once on Day 1 and then QD on Days 8 to 35 of Cycle 1 (Cycle 1 duration=35 days) and in subsequent 28-day cycles until disease progression.

Arm type	Experimental
Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Participants received GDC-0032 16 mg capsules, orally, once on Day 1 and then QD on Days 8 to 35 of Cycle 1 (Cycle 1 duration=35 days) and in subsequent 28-day cycles.

Arm title	Phase I, Stage 2: Cohort A - GDC-0032 9 mg QD

Arm description:

Participants with PIK3CA-mutant breast cancer were enrolled in this cohort to receive GDC-0032 9 mg capsules, orally, once on Day 1 and then QD on Days 8 to 35 of Cycle 1 (Cycle 1 duration=35 days) and in subsequent 28-day cycles until disease progression.

Arm type	Experimental
Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Participants received GDC-0032 9 mg capsules, orally, once on Day 1 and then QD on Days 8 to 35 of Cycle 1 (Cycle 1 duration=35 days) and in subsequent 28-day cycles.

Arm title	Phase I, Stage 2: Cohort B - GDC-0032 9 mg QD

Arm description:

Participants with PIK3CA-mutant solid tumors other than breast cancer were enrolled in this cohort to receive GDC-0032 9 mg capsules, orally, QD in 28-day cycles until disease progression.

Arm type	Experimental

Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Participants received GDC-0032 9 mg capsules, orally, QD in 28-day cycles.

Arm title	Phase I, Stage 2: Cohort C -GDC-0032 9 mg QD + Mida 5 mg

Arm description:

Participants with any type of solid tumors were enrolled in this cohort to receive GDC-0032 9 mg capsules, orally, QD on Days 2 to 29 along with midazolam 5 mg syrup, orally, once on Days 1 and 16 of Cycle 1 (Cycle 1 duration=29 days) followed by GDC-0032 9 mg capsules, orally, QD in subsequent 28-day cycles until disease progression.

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

Dosage and administration details:

Participants received midazolam 5 mg syrup, orally, once on Days 1 and 16 of Cycle 1 (Cycle 1 duration=29 days) and QD in subsequent 28-day cycles.

Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Participants received GDC-0032 9 mg capsules, orally, QD on Days 2 to 29 and QD in subsequent 28-day cycles.

Arm title	Phase I, Stage 2: Cohort D - GDC-0032 9 mg QD

Arm description:

Participants with HER2-positive breast cancer were enrolled in this cohort to receive GDC-0032 9 mg capsules, orally, QD in 28-day cycles until disease progression.

Arm type	Experimental
Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032
Pharmaceutical forms	Capsule, soft, Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Participants received GDC-0032 9 mg capsules, orally, QD in 28-day cycles.

Arm title	Phase I, Stage 2: Cohort E –GDC-0032 6 mg QD + Letro 2.5 mg QD

Arm description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 6 mg and letrozole 2.5 mg capsules, orally, QD in 28-day cycles until disease progression.

Arm type	Experimental

Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032
	Capsule, hard

Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Participants received GDC-0032 6 mg capsules, orally, QD in 28-day cycles.

Arm title	Phase I, Stage 2: Cohort F - GDC-0032 9 mg QD + Fulv 500 mg

Arm description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 9 mg capsules, orally, QD in 28-day cycles along with fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycle until disease progression.

Arm type	Experimental
Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Participants received GDC-0032 9 mg capsules, orally, QD in 28-day cycles.

Investigational medicinal product name	Fulvestrant
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycle.

Arm title	Phase I, Stage 2: Cohort G - GDC-0032 9 mg QD

Arm description:

Participants with solid tumors with increased PIK3CA copy number were enrolled in this cohort to receive GDC-0032 9 mg capsules, orally, QD in each 28-day cycle until disease progression.

Arm type	Experimental
Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Participants received GDC-0032 9 mg capsules, orally, QD in 28-day cycles.

Arm title	Phase I, Stage 2: Cohort H - GDC-0032 6 mg QD

Arm description:

Participants with PIK3CA-mutant solid tumors that are non-breast and non-colorectal cancer were enrolled in this cohort to receive GDC-0032 6 mg tablets, orally, QD on Days 1 to 21 of each 28-day cycle until disease progression.

Arm type	Experimental
Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received GDC-0032 6 mg tablets, orally, QD on Days 1 to 21 of each 28-day cycle.

Arm title	Phase I, Stage 2: Cohort J - GDC-0032 4 mg + Fulv 500 mg

Arm description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally, QD on Days 1 to 21 of each 28-day cycle along with fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycle until disease progression.

Arm type	Experimental
Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received GDC-0032 4 mg tablets, orally, QD on Days 1 to 21 of each 28-day cycle.

Investigational medicinal product name	Fulvestrant
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycle.

Arm title	Phase I, Stage 2: Cohort K - GDC-0032 4 mg + Fulv 500 mg

Arm description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally, QD on Days 1-5, 8-12, 15-19, and 22-26 of each 28-day cycle along with fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycle until disease progression.

Arm type	Experimental
Investigational medicinal product name	Fulvestrant
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycle.

Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received GDC-0032 4 mg tablets, orally, QD on Days 1-5, 8-12, 15-19, and 22-26 of each 28-day cycle.

Arm title	Phase I, Stage 2: Cohort L - GDC-0032 4 mg + Fulv 500 mg

Arm description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally, QD on Days 1-7 and 15-21 of each 28-day cycle along with fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycle until disease progression.

Arm type	Experimental

Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received GDC-0032 4 mg tablets, orally, QD on Days 1-7 and 15-21 of each 28-day cycle.

Investigational medicinal product name	Fulvestrant
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycle.

Arm title	Phase I, Stage 2: Cohort M - GDC-0032 2 mg QD + Fulv 500 mg

Arm description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 2 mg tablets, orally, QD in each 28-day cycle along with fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycle until disease progression.

Arm type	Experimental
Investigational medicinal product name	Fulvestrant
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycle.

Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received GDC-0032 2 mg tablets, orally, QD in 28-day cycles.

Arm title	Phase I, Stage 2: Cohort N -GDC-0032 2 mg QD + Letro 2.5 mg QD

Arm description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 2 mg tablets and letrozole 2.5 mg capsules, orally, QD in 28-day cycles until disease progression.

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

Dosage and administration details:

Participants received letrozole 2.5 mg capsules, orally, QD in 28-day cycles.

Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032

Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received GDC-0032 2 mg tablets, orally, QD in 28-day cycles.

Arm title	Phase I, Stage 2: Cohort P -GDC-0032 4 mg QD + Letro 2.5 mg QD

Arm description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 4 mg tablets and letrozole 2.5 mg capsules, orally, QD in 28-day cycles until disease progression.

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

Dosage and administration details:

Participants received letrozole 2.5 mg capsules, orally, QD in 28-day cycles.

Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received GDC-0032 4 mg tablets, orally, QD in 28-day cycles.

Arm title	Phase I, Stage 2: Cohort Q - GDC-0032 4 mg + Letro 2.5 mg QD

Arm description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally, QD on Days 1 to 21 along with letrozole 2.5 mg capsules, orally, QD in 28-day cycles until disease progression.

Arm type	Experimental
Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received GDC-0032 4 mg tablets, orally, QD on Days 1 to 21 in 28-day cycles.

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

Dosage and administration details:

Participants received letrozole 2.5 mg capsules, orally, QD in 28-day cycles.

Arm title	Phase I, Stage 2: Cohort R - GDC-0032 4 mg + Letro 2.5 mg QD

Arm description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally on Days 1-5, 8-12, 15-19, and 22-26 along with letrozole 2.5 mg capsules, orally, QD in 28-day cycles until disease progression.

Arm type	Experimental

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

Dosage and administration details:

Participants received letrozole 2.5 mg capsules, orally, QD in 28-day cycles.

Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received GDC-0032 4 mg tablets, orally on Days 1-5, 8-12, 15-19, and 22-26 of each 28-day cycle.

Arm title	Phase I, Stage 2: Cohort S - GDC-0032 4 mg + Letro 2.5 mg QD

Arm description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally on Days 1-7 and 15-21 along with letrozole 2.5 mg capsules, orally, QD in 28-day cycles until disease progression.

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

Dosage and administration details:

Participants received letrozole 2.5 mg capsules, orally, QD in 28-day cycles.

Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received GDC-0032 4 mg tablets, orally on Days 1-7 and 15-21 of each 28-day cycle.

Arm title	Phase I, Stage 2: Cohort T - GDC-0032 4 mg QD

Arm description:

Participants with non-Hodgkin’s lymphoma that had progressed or had failed to respond to at least one prior regimen were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally QD in 28-day cycles until disease progression.

Arm type	Experimental
Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received GDC-0032 4 mg tablets, orally QD in 28-day cycles.

Arm title	Phase I, Stage 2: Cohort T2 - GDC-0032 4 mg QD

Arm description:

Participants with DLBCL who had progressed or had failed to respond to at least one prior regimen were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally, QD in 28-day cycles until disease

progression.

Arm type	Experimental
Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received GDC-0032 4 mg tablets, orally, QD in 28-day cycles.

Arm title	Phase I, Stage 2: Cohort X - GDC-0032 4 mg QD

Arm description:

Participants with PIK3CA-mutant solid tumors that have progressed or failed to respond to at least one prior regimen were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally, QD in 28-day cycles until disease progression.

Arm type	Experimental
Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received GDC-0032 4 mg tablets, orally, QD in 28-day cycles.

Arm title	Phase I, Stage 2: Cohort X - GDC-0032 6 mg QD

Arm description:

Participants with PIK3CA-mutant solid tumors that had progressed or failed to respond to at least one prior regimen were enrolled in this cohort to receive GDC-0032 6 mg tablets, orally QD in 28-day cycles until disease progression.

Arm type	Experimental
Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received GDC-0032 6 mg tablets, orally QD in 28-day cycles.

Arm title	Phase II: GDC-0032 6 mg QD + Fulv 500 mg

Arm description:

Postmenopausal participants with locally advanced or metastatic HER2-negative, hormone receptor-positive breast cancer who had not previously received fulvestrant were enrolled in this cohort to receive GDC-0032 6 mg tablets, orally, QD in 28-day cycles along with fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycles until disease progression.

Arm type	Experimental
Investigational medicinal product name	Fulvestrant
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycle.

Investigational medicinal product name	Taselisib
Investigational medicinal product code	
Other name	GDC-0032

Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received GDC-0032 6 mg tablets, orally, QD in 28-day cycles.

Number of subjects in period 1	Phase I, Stage 1: GDC-0032 3 milligrams (mg) once daily (QD)	Phase I, Stage 1: GDC-0032 5 mg QD	Phase I, Stage 1: GDC-0032 8 mg QD
Started	6	3	4
Completed	0	0	0
Not completed	6	3	4
Adverse event, serious fatal	-	-	-
Physician decision	-	-	-
Consent withdrawn by subject	-	-	-
Use of Another Anti-Cancer Therapy	-	-	-
Adverse event, non-fatal	-	-	1
Study Terminated By Sponsor	-	-	-
Reason Not Specified	-	-	-
Progressive Disease	6	3	3
Non-Compliance With Study Drug	-	-	-
Lost to follow-up	-	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	Phase I, Stage 1: GDC-0032 12 mg QD	Phase I, Stage 1: GDC-0032 16 mg QD	Phase I, Stage 2: Cohort A - GDC-0032 9 mg QD
Started	10	11	20
Completed	0	0	0
Not completed	10	11	20
Adverse event, serious fatal	2	1	-
Physician decision	-	1	-
Consent withdrawn by subject	-	1	-
Use of Another Anti-Cancer Therapy	-	-	-
Adverse event, non-fatal	1	2	4
Study Terminated By Sponsor	-	-	-
Reason Not Specified	-	-	-
Progressive Disease	7	6	16
Non-Compliance With Study Drug	-	-	-
Lost to follow-up	-	-	-

Protocol deviation	-	-	-

Number of subjects in period 1	Phase I, Stage 2: Cohort B - GDC-0032 9 mg QD	Phase I, Stage 2: Cohort C -GDC-0032 9 mg QD + Mida 5 mg	Phase I, Stage 2: Cohort D - GDC-0032 9 mg QD
Started	20	13	10
Completed	0	0	0
Not completed	20	13	10
Adverse event, serious fatal	2	-	-
Physician decision	-	-	-
Consent withdrawn by subject	1	-	-
Use of Another Anti-Cancer Therapy	-	-	-
Adverse event, non-fatal	1	4	3
Study Terminated By Sponsor	-	-	-
Reason Not Specified	-	-	-
Progressive Disease	16	8	7
Non-Compliance With Study Drug	-	1	-
Lost to follow-up	-	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	Phase I, Stage 2: Cohort E –GDC-0032 6 mg QD + Letro 2.5 mg QD	Phase I, Stage 2: Cohort E -GDC-0032 9 mg QD + Letro 2.5 mg QD	Phase I, Stage 2: Cohort F - GDC-0032 6 mg QD + Fulv 500 mg
Started	20	8	21
Completed	0	0	1
Not completed	20	8	20
Adverse event, serious fatal	1	-	1
Physician decision	-	-	-
Consent withdrawn by subject	-	1	1
Use of Another Anti-Cancer Therapy	-	-	-
Adverse event, non-fatal	1	-	4
Study Terminated By Sponsor	-	-	-
Reason Not Specified	-	-	-
Progressive Disease	18	7	14
Non-Compliance With Study Drug	-	-	-
Lost to follow-up	-	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	Phase I, Stage 2: Cohort F - GDC-0032 9 mg QD + Fulv 500 mg	Phase I, Stage 2: Cohort G - GDC-0032 9 mg QD	Phase I, Stage 2: Cohort H - GDC-0032 6 mg QD
Started	6	21	35
Completed	0	0	0
Not completed	6	21	35

Adverse event, serious fatal	-	2	27
Physician decision	-	1	-
Consent withdrawn by subject	-	-	3
Use of Another Anti-Cancer Therapy	-	-	-
Adverse event, non-fatal	1	4	-
Study Terminated By Sponsor	-	-	-
Reason Not Specified	-	1	2
Progressive Disease	5	12	1
Non-Compliance With Study Drug	-	-	-
Lost to follow-up	-	-	2
Protocol deviation	-	1	-

Number of subjects in period 1	Phase I, Stage 2: Cohort J - GDC-0032 4 mg + Fulv 500 mg	Phase I, Stage 2: Cohort K - GDC-0032 4 mg + Fulv 500 mg	Phase I, Stage 2: Cohort L - GDC-0032 4 mg + Fulv 500 mg
Started	20	20	19
Completed	0	0	1
Not completed	20	20	18
Adverse event, serious fatal	15	11	11
Physician decision	-	-	-
Consent withdrawn by subject	-	2	1
Use of Another Anti-Cancer Therapy	-	-	-
Adverse event, non-fatal	-	-	-
Study Terminated By Sponsor	-	-	-
Reason Not Specified	3	7	4
Progressive Disease	1	-	-
Non-Compliance With Study Drug	-	-	-
Lost to follow-up	1	-	2
Protocol deviation	-	-	-

Number of subjects in period 1	Phase I, Stage 2: Cohort M - GDC-0032 2 mg QD + Fulv 500 mg	Phase I, Stage 2: Cohort N -GDC-0032 2 mg QD + Letro 2.5 mg QD	Phase I, Stage 2: Cohort P -GDC-0032 4 mg QD + Letro 2.5 mg QD
Started	20	27	28
Completed	0	0	0
Not completed	20	27	28
Adverse event, serious fatal	17	12	13
Physician decision	-	1	-
Consent withdrawn by subject	-	1	1
Use of Another Anti-Cancer Therapy	-	2	-
Adverse event, non-fatal	-	1	-
Study Terminated By Sponsor	-	-	-

Reason Not Specified	3	7	11
Progressive Disease	-	1	-
Non-Compliance With Study Drug	-	-	-
Lost to follow-up	-	2	3
Protocol deviation	-	-	-

Number of subjects in period 1	Phase I, Stage 2: Cohort Q - GDC-0032 4 mg + Letro 2.5 mg QD	Phase I, Stage 2: Cohort R - GDC-0032 4 mg + Letro 2.5 mg QD	Phase I, Stage 2: Cohort S - GDC-0032 4 mg + Letro 2.5 mg QD
Started	20	20	20
Completed	0	0	0
Not completed	20	20	20
Adverse event, serious fatal	12	12	13
Physician decision	-	-	-
Consent withdrawn by subject	1	3	-
Use of Another Anti-Cancer Therapy	-	-	-
Adverse event, non-fatal	-	-	-
Study Terminated By Sponsor			

	0032 6 mg QD	mg
Started	122	60
Completed	1	0
Not completed	121	60
Adverse event, serious fatal	92	44
Physician decision	-	-
Consent withdrawn by subject	4	2
Use of Another Anti-Cancer Therapy	-	-
Adverse event, non-fatal	-	-
Study Terminated By Sponsor	-	-
Reason Not Specified	11	9
Progressive Disease	1	-
Non-Compliance With Study Drug	-	-
Lost to follow-up	13	5
Protocol deviation	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Phase I, Stage 1: GDC-0032 3 milligrams (mg) once daily (QD)
Reporting group description:	
Participants received GDC-0032 3 mg capsules, orally, once on Day 1 and then QD on Days 8 to 35 of Cycle 1 (Cycle 1 duration=35 days) and in subsequent 28-day cycles until disease progression.	
Reporting group title	Phase I, Stage 1: GDC-0032 5 mg QD
Reporting group description:	
Participants received GDC-0032 5 mg capsules, orally, once on Day 1 and then QD on Days 8 to 35 of Cycle 1 (Cycle 1 duration=35 days) and in subsequent 28-day cycles until disease progression.	
Reporting group title	Phase I, Stage 1: GDC-0032 8 mg QD
Reporting group description:	
Participants received GDC-0032 8 mg capsules, orally, once on Day 1 and then QD on Days 8 to 35 of Cycle 1 (Cycle 1 duration=35 days) and in subsequent 28-day cycles until disease progression.	
Reporting group title	Phase I, Stage 1: GDC-0032 12 mg QD
Reporting group description:	
Participants received GDC-0032 12 mg capsules, orally, once on Day 1 and then QD on Days 8 to 35 of Cycle 1 (Cycle 1 duration=35 days) and in subsequent 28-day cycles until disease progression.	
Reporting group title	Phase I, Stage 1: GDC-0032 16 mg QD
Reporting group description:	
Participants received GDC-0032 16 mg capsules, orally, once on Day 1 and then QD on Days 8 to 35 of Cycle 1 (Cycle 1 duration=35 days) and in subsequent 28-day cycles until disease progression.	
Reporting group title	Phase I, Stage 2: Cohort A - GDC-0032 9 mg QD
Reporting group description:	
Participants with PIK3CA-mutant breast cancer were enrolled in this cohort to receive GDC-0032 9 mg capsules, orally, once on Day 1 and then QD on Days 8 to 35 of Cycle 1 (Cycle 1 duration=35 days) and in subsequent 28-day cycles until disease progression.	
Reporting group title	Phase I, Stage 2: Cohort B - GDC-0032 9 mg QD
Reporting group description:	
Participants with PIK3CA-mutant solid tumors other than breast cancer were enrolled in this cohort to receive GDC-0032 9 mg capsules, orally, QD in 28-day cycles until disease progression.	
Reporting group title	Phase I, Stage 2: Cohort C -GDC-0032 9 mg QD + Mida 5 mg
Reporting group description:	
Participants with any type of solid tumors were enrolled in this cohort to receive GDC-0032 9 mg capsules, orally, QD on Days 2 to 29 along with midazolam 5 mg syrup, orally, once on Days 1 and 16 of Cycle 1 (Cycle 1 duration=29 days) followed by GDC-0032 9 mg capsules, orally, QD in subsequent 28-day cycles until disease progression.	
Reporting group title	Phase I, Stage 2: Cohort D - GDC-0032 9 mg QD
Reporting group description:	
Participants with HER2-positive breast cancer were enrolled in this cohort to receive GDC-0032 9 mg capsules, orally, QD in 28-day cycles until disease progression.	
Reporting group title	Phase I, Stage 2: Cohort E –GDC-0032 6 mg QD + Letro 2.5 mg QD
Reporting group description:	
Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 6 mg and letrozole 2.5 mg capsules, orally, QD in 28-day cycles until disease progression.	
Reporting group title	Phase I, Stage 2: Cohort E -GDC-0032 9 mg QD + Letro 2.5 mg QD
Reporting group description:	
Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 9 mg and letrozole 2.5 mg capsules, orally, QD in 28-day cycles until disease progression.	
Reporting group title	Phase I, Stage 2: Cohort F - GDC-0032 6 mg QD + Fulv 500 mg

Reporting group description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 6 mg capsules, orally, QD in 28-day cycles along with fulvestrant 500 mg, intramuscularly (IM) on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycle until disease progression.

Reporting group title	Phase I, Stage 2: Cohort F - GDC-0032 9 mg QD + Fulv 500 mg

Reporting group description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 9 mg capsules, orally, QD in 28-day cycles along with fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycle until disease progression.

Reporting group title	Phase I, Stage 2: Cohort G - GDC-0032 9 mg QD

Reporting group description:

Participants with solid tumors with increased PIK3CA copy number were enrolled in this cohort to receive GDC-0032 9 mg capsules, orally, QD in each 28-day cycle until disease progression.

Reporting group title	Phase I, Stage 2: Cohort H - GDC-0032 6 mg QD

Reporting group description:

Participants with PIK3CA-mutant solid tumors that are non-breast and non-colorectal cancer were enrolled in this cohort to receive GDC-0032 6 mg tablets, orally, QD on Days 1 to 21 of each 28-day cycle until disease progression.

Reporting group title	Phase I, Stage 2: Cohort J - GDC-0032 4 mg + Fulv 500 mg

Reporting group description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally, QD on Days 1 to 21 of each 28-day cycle along with fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycle until disease progression.

Reporting group title	Phase I, Stage 2: Cohort K - GDC-0032 4 mg + Fulv 500 mg

Reporting group description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally, QD on Days 1-5, 8-12, 15-19, and 22-26 of each 28-day cycle along with fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycle until disease progression.

Reporting group title	Phase I, Stage 2: Cohort L - GDC-0032 4 mg + Fulv 500 mg

Reporting group description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally, QD on Days 1-7 and 15-21 of each 28-day cycle along with fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycle until disease progression.

Reporting group title	Phase I, Stage 2: Cohort M - GDC-0032 2 mg QD + Fulv 500 mg

Reporting group description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 2 mg tablets, orally, QD in each 28-day cycle along with fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycle until disease progression.

Reporting group title	Phase I, Stage 2: Cohort N -GDC-0032 2 mg QD + Letro 2.5 mg QD

Reporting group description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 2 mg tablets and letrozole 2.5 mg capsules, orally, QD in 28-day cycles until disease progression.

Reporting group title	Phase I, Stage 2: Cohort P -GDC-0032 4 mg QD + Letro 2.5 mg QD

Reporting group description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 4 mg tablets and letrozole 2.5 mg capsules, orally, QD in 28-day cycles until disease progression.

Reporting group title	Phase I, Stage 2: Cohort Q - GDC-0032 4 mg + Letro 2.5 mg QD

Reporting group description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort

to receive GDC-0032 4 mg tablets, orally, QD on Days 1 to 21 along with letrozole 2.5 mg capsules, orally, QD in 28-day cycles until disease progression.

Reporting group title	Phase I, Stage 2: Cohort R - GDC-0032 4 mg + Letro 2.5 mg QD

Reporting group description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally on Days 1-5, 8-12, 15-19, and 22-26 along with letrozole 2.5 mg capsules, orally, QD in 28-day cycles until disease progression.

Reporting group title	Phase I, Stage 2: Cohort S - GDC-0032 4 mg + Letro 2.5 mg QD

Reporting group description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally on Days 1-7 and 15-21 along with letrozole 2.5 mg capsules, orally, QD in 28-day cycles until disease progression.

Reporting group title	Phase I, Stage 2: Cohort T - GDC-0032 4 mg QD

Reporting group description:

Participants with non-Hodgkin’s lymphoma that had progressed or had failed to respond to at least one prior regimen were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally QD in 28-day cycles until disease progression.

Reporting group title	Phase I, Stage 2: Cohort T2 - GDC-0032 4 mg QD

Reporting group description:

Participants with DLBCL who had progressed or had failed to respond to at least one prior regimen were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally, QD in 28-day cycles until disease progression.

Reporting group title	Phase I, Stage 2: Cohort X - GDC-0032 4 mg QD

Reporting group description:

Participants with PIK3CA-mutant solid tumors that have progressed or failed to respond to at least one prior regimen were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally, QD in 28-day cycles until disease progression.

Reporting group title	Phase I, Stage 2: Cohort X - GDC-0032 6 mg QD

Reporting group description:

Participants with PIK3CA-mutant solid tumors that had progressed or failed to respond to at least one prior regimen were enrolled in this cohort to receive GDC-0032 6 mg tablets, orally QD in 28-day cycles until disease progression.

Reporting group title	Phase II: GDC-0032 6 mg QD + Fulv 500 mg

Reporting group description:

Postmenopausal participants with locally advanced or metastatic HER2-negative, hormone receptor-positive breast cancer who had not previously received fulvestrant were enrolled in this cohort to receive GDC-0032 6 mg tablets, orally, QD in 28-day cycles along with fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycles until disease progression.

Reporting group values	Phase I, Stage 1: GDC-0032 3 milligrams (mg) once daily (QD)	Phase I, Stage 1: GDC-0032 5 mg QD	Phase I, Stage 1: GDC-0032 8 mg QD
Number of subjects	6	3	4
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	51.0	49.0	66.3
standard deviation	± 9.2	± 12.5	± 12.8
Sex: Female, Male Units: participants			
Female	4	2	2

Male	2	1	2

Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Black or African American	0	0	0
Native Hawaiian or other Pacific Islande	0	0	0
White	6	3	4
Other	0	0	0
Multiple	0	0	0
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	5	3	4
Unknown	0	0	0
Not Reported	0	0	0

Reporting group values	Phase I, Stage 1: GDC-0032 12 mg QD	Phase I, Stage 1: GDC-0032 16 mg QD	Phase I, Stage 2: Cohort A - GDC-0032 9 mg QD
Number of subjects	10	11	20
Age categorical Units: Subjects			

Age Continuous Units: years			
arithmetic mean	60.7	57.9	56.8
standard deviation	± 15.4	± 11.9	± 11.6
Sex: Female, Male Units: participants			
Female	9	6	19
Male	1	5	1
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	1	0
Black or African American	1	0	1
Native Hawaiian or other Pacific Islande	0	1	0
White	8	8	18
Other	0	1	1
Multiple	0	0	0
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	1	0	1
Not Hispanic or Latino	7	10	19
Unknown	2	0	0
Not Reported	0	1	0

Reporting group values	Phase I, Stage 2: Cohort B - GDC-0032 9 mg QD	Phase I, Stage 2: Cohort C -GDC-0032 9 mg QD + Mida 5 mg	Phase I, Stage 2: Cohort D - GDC-0032 9 mg QD
Number of subjects	20	13	10
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	62.6	61.7	50.4
standard deviation	± 11.9	± 9.6	± 9.5
Sex: Female, Male Units: participants			
Female	12	6	10
Male	8	7	0
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Black or African American	0	0	0
Native Hawaiian or other Pacific Islande	0	0	0
White	20	12	10
Other	0	1	0
Multiple	0	0	0
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	20	12	9
Unknown	0	1	0
Not Reported	0	0	1

Reporting group values	Phase I, Stage 2: Cohort E –GDC-0032 6 mg QD + Letro 2.5 mg QD	Phase I, Stage 2: Cohort E -GDC-0032 9 mg QD + Letro 2.5 mg QD	Phase I, Stage 2: Cohort F - GDC-0032 6 mg QD + Fulv 500 mg
Number of subjects	20	8	21
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	63.5	59.1	59.8
standard deviation	± 9.7	± 7.6	± 11.9
Sex: Female, Male Units: participants			
Female	20	8	21
Male	0	0	0
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	1

Black or African American	0	0	0
Native Hawaiian or other Pacific Islande	0	0	0
White	20	8	19
Other	0	0	1
Multiple	0	0	0
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	0	0	1
Not Hispanic or Latino	18	8	20
Unknown	1	0	0
Not Reported	1	0	0

Reporting group values	Phase I, Stage 2: Cohort F - GDC-0032 9 mg QD + Fulv 500 mg	Phase I, Stage 2: Cohort G - GDC-0032 9 mg QD	Phase I, Stage 2: Cohort H - GDC-0032 6 mg QD
Number of subjects	6	21	35
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	55.0	64.4	64.3
standard deviation	± 9.7	± 10.0	± 11.8
Sex: Female, Male Units: participants			
Female	6	16	22
Male	0	5	13
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	1	0
Asian	0	0	1
Black or African American	0	0	1
Native Hawaiian or other Pacific Islande	0	0	0
White	6	20	30
Other	0	0	3
Multiple	0	0	0
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	0	2	1
Not Hispanic or Latino	6	18	31
Unknown	0	1	0
Not Reported	0	0	3

Reporting group values	Phase I, Stage 2: Cohort J - GDC-0032 4 mg + Fulv 500 mg	Phase I, Stage 2: Cohort K - GDC-0032 4 mg + Fulv 500 mg	Phase I, Stage 2: Cohort L - GDC-0032 4 mg + Fulv 500 mg
Number of subjects	20	20	19
Age categorical Units: Subjects			

Age Continuous Units: years			
arithmetic mean	61.8	62.8	54.3
standard deviation	± 7.7	± 9.1	± 12.7
Sex: Female, Male Units: participants			
Female	20	20	19
Male	0	0	0
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	1
Black or African American	1	0	1
Native Hawaiian or other Pacific Islande	0	0	0
White	19	20	17
Other	0	0	0
Multiple	0	0	0
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	2	0	1
Not Hispanic or Latino	17	20	17
Unknown	0	0	0
Not Reported	1	0	1

Reporting group values	Phase I, Stage 2: Cohort M - GDC-0032 2 mg QD + Fulv 500 mg	Phase I, Stage 2: Cohort N -GDC-0032 2 mg QD + Letro 2.5 mg QD	Phase I, Stage 2: Cohort P -GDC-0032 4 mg QD + Letro 2.5 mg QD
Number of subjects	20	27	28
Age categorical Units: Subjects			

Age Continuous Units: years			
arithmetic mean	55.7	63.1	59.7
standard deviation	± 11.9	± 9.1	± 12.5
Sex: Female, Male Units: participants			
Female	20	27	28
Male	0	0	0
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	2	1	0
Black or African American	0	0	1
Native Hawaiian or other Pacific Islande	0	0	0
White	17	26	27
Other	1	0	0
Multiple	0	0	0
Race/Ethnicity, Customized Units: Subjects			

Hispanic or Latino	0	0	2
Not Hispanic or Latino	18	24	25
Unknown	1	0	0
Not Reported	1	3	1

Reporting group values	Phase I, Stage 2: Cohort Q - GDC-0032 4 mg + Letro 2.5 mg QD	Phase I, Stage 2: Cohort R - GDC-0032 4 mg + Letro 2.5 mg QD	Phase I, Stage 2: Cohort S - GDC-0032 4 mg + Letro 2.5 mg QD
Number of subjects	20	20	20
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	57.2	58.3	59.5
standard deviation	± 13.9	± 8.9	± 10.6
Sex: Female, Male Units: participants			
Female	20	20	19
Male	0	0	1
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	0	0
Black or African American	1	2	0
Native Hawaiian or other Pacific Islande	0	0	0
White	18	18	20
Other	0	0	0
Multiple	0	0	0
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	18	19	20
Unknown	0	0	0
Not Reported	1	1	0

Reporting group values	Phase I, Stage 2: Cohort T - GDC-0032 4 mg QD	Phase I, Stage 2: Cohort T2 - GDC-0032 4 mg QD	Phase I, Stage 2: Cohort X - GDC-0032 4 mg QD
Number of subjects	10	10	70
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	66.1	53.9	60.6
standard deviation	± 7.8	± 19.3	± 13.4
Sex: Female, Male Units: participants			
Female	6	2	37
Male	4	8	33

Race/Ethnicity, Customized				
Units: Subjects				
American Indian or Alaska Native	0	1	0	
Asian	0	0	4	
Black or African American	0			

End points

End points reporting groups

Reporting group title	Phase I, Stage 1: GDC-0032 3 milligrams (mg) once daily (QD)
Reporting group description:	
Participants received GDC-0032 3 mg capsules, orally, once on Day 1 and then QD on Days 8 to 35 of Cycle 1 (Cycle 1 duration=35 days) and in subsequent 28-day cycles until disease progression.	
Reporting group title	Phase I, Stage 1: GDC-0032 5 mg QD
Reporting group description:	
Participants received GDC-0032 5 mg capsules, orally, once on Day 1 and then QD on Days 8 to 35 of Cycle 1 (Cycle 1 duration=35 days) and in subsequent 28-day cycles until disease progression.	
Reporting group title	Phase I, Stage 1: GDC-0032 8 mg QD
Reporting group description:	
Participants received GDC-0032 8 mg capsules, orally, once on Day 1 and then QD on Days 8 to 35 of Cycle 1 (Cycle 1 duration=35 days) and in subsequent 28-day cycles until disease progression.	
Reporting group title	Phase I, Stage 1: GDC-0032 12 mg QD
Reporting group description:	
Participants received GDC-0032 12 mg capsules, orally, once on Day 1 and then QD on Days 8 to 35 of Cycle 1 (Cycle 1 duration=35 days) and in subsequent 28-day cycles until disease progression.	
Reporting group title	Phase I, Stage 1: GDC-0032 16 mg QD
Reporting group description:	
Participants received GDC-0032 16 mg capsules, orally, once on Day 1 and then QD on Days 8 to 35 of Cycle 1 (Cycle 1 duration=35 days) and in subsequent 28-day cycles until disease progression.	
Reporting group title	Phase I, Stage 2: Cohort A - GDC-0032 9 mg QD
Reporting group description:	
Participants with PIK3CA-mutant breast cancer were enrolled in this cohort to receive GDC-0032 9 mg capsules, orally, once on Day 1 and then QD on Days 8 to 35 of Cycle 1 (Cycle 1 duration=35 days) and in subsequent 28-day cycles until disease progression.	
Reporting group title	Phase I, Stage 2: Cohort B - GDC-0032 9 mg QD
Reporting group description:	
Participants with PIK3CA-mutant solid tumors other than breast cancer were enrolled in this cohort to receive GDC-0032 9 mg capsules, orally, QD in 28-day cycles until disease progression.	
Reporting group title	Phase I, Stage 2: Cohort C -GDC-0032 9 mg QD + Mida 5 mg
Reporting group description:	
Participants with any type of solid tumors were enrolled in this cohort to receive GDC-0032 9 mg capsules, orally, QD on Days 2 to 29 along with midazolam 5 mg syrup, orally, once on Days 1 and 16 of Cycle 1 (Cycle 1 duration=29 days) followed by GDC-0032 9 mg capsules, orally, QD in subsequent 28-day cycles until disease progression.	
Reporting group title	Phase I, Stage 2: Cohort D - GDC-0032 9 mg QD
Reporting group description:	
Participants with HER2-positive breast cancer were enrolled in this cohort to receive GDC-0032 9 mg capsules, orally, QD in 28-day cycles until disease progression.	
Reporting group title	Phase I, Stage 2: Cohort E –GDC-0032 6 mg QD + Letro 2.5 mg QD
Reporting group description:	
Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 6 mg and letrozole 2.5 mg capsules, orally, QD in 28-day cycles until disease progression.	
Reporting group title	Phase I, Stage 2: Cohort E -GDC-0032 9 mg QD + Letro 2.5 mg QD
Reporting group description:	
Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 9 mg and letrozole 2.5 mg capsules, orally, QD in 28-day cycles until disease progression.	
Reporting group title	Phase I, Stage 2: Cohort F - GDC-0032 6 mg QD + Fulv 500 mg

Reporting group description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 6 mg capsules, orally, QD in 28-day cycles along with fulvestrant 500 mg, intramuscularly (IM) on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycle until disease progression.

Reporting group title	Phase I, Stage 2: Cohort F - GDC-0032 9 mg QD + Fulv 500 mg

Reporting group description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 9 mg capsules, orally, QD in 28-day cycles along with fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycle until disease progression.

Reporting group title	Phase I, Stage 2: Cohort G - GDC-0032 9 mg QD

Reporting group description:

Participants with solid tumors with increased PIK3CA copy number were enrolled in this cohort to receive GDC-0032 9 mg capsules, orally, QD in each 28-day cycle until disease progression.

Reporting group title	Phase I, Stage 2: Cohort H - GDC-0032 6 mg QD

Reporting group description:

Participants with PIK3CA-mutant solid tumors that are non-breast and non-colorectal cancer were enrolled in this cohort to receive GDC-0032 6 mg tablets, orally, QD on Days 1 to 21 of each 28-day cycle until disease progression.

Reporting group title	Phase I, Stage 2: Cohort J - GDC-0032 4 mg + Fulv 500 mg

Reporting group description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally, QD on Days 1 to 21 of each 28-day cycle along with fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycle until disease progression.

Reporting group title	Phase I, Stage 2: Cohort K - GDC-0032 4 mg + Fulv 500 mg

Reporting group description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally, QD on Days 1-5, 8-12, 15-19, and 22-26 of each 28-day cycle along with fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycle until disease progression.

Reporting group title	Phase I, Stage 2: Cohort L - GDC-0032 4 mg + Fulv 500 mg

Reporting group description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally, QD on Days 1-7 and 15-21 of each 28-day cycle along with fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycle until disease progression.

Reporting group title	Phase I, Stage 2: Cohort M - GDC-0032 2 mg QD + Fulv 500 mg

Reporting group description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 2 mg tablets, orally, QD in each 28-day cycle along with fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycle until disease progression.

Reporting group title	Phase I, Stage 2: Cohort N -GDC-0032 2 mg QD + Letro 2.5 mg QD

Reporting group description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 2 mg tablets and letrozole 2.5 mg capsules, orally, QD in 28-day cycles until disease progression.

Reporting group title	Phase I, Stage 2: Cohort P -GDC-0032 4 mg QD + Letro 2.5 mg QD

Reporting group description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 4 mg tablets and letrozole 2.5 mg capsules, orally, QD in 28-day cycles until disease progression.

Reporting group title	Phase I, Stage 2: Cohort Q - GDC-0032 4 mg + Letro 2.5 mg QD

Reporting group description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort

to receive GDC-0032 4 mg tablets, orally, QD on Days 1 to 21 along with letrozole 2.5 mg capsules, orally, QD in 28-day cycles until disease progression.

Reporting group title	Phase I, Stage 2: Cohort R - GDC-0032 4 mg + Letro 2.5 mg QD

Reporting group description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally on Days 1-5, 8-12, 15-19, and 22-26 along with letrozole 2.5 mg capsules, orally, QD in 28-day cycles until disease progression.

Reporting group title	Phase I, Stage 2: Cohort S - GDC-0032 4 mg + Letro 2.5 mg QD

Reporting group description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally on Days 1-7 and 15-21 along with letrozole 2.5 mg capsules, orally, QD in 28-day cycles until disease progression.

Reporting group title	Phase I, Stage 2: Cohort T - GDC-0032 4 mg QD

Reporting group description:

Participants with non-Hodgkin’s lymphoma that had progressed or had failed to respond to at least one prior regimen were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally QD in 28-day cycles until disease progression.

Reporting group title	Phase I, Stage 2: Cohort T2 - GDC-0032 4 mg QD

Reporting group description:

Participants with DLBCL who had progressed or had failed to respond to at least one prior regimen were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally, QD in 28-day cycles until disease progression.

Reporting group title	Phase I, Stage 2: Cohort X - GDC-0032 4 mg QD

Reporting group description:

Participants with PIK3CA-mutant solid tumors that have progressed or failed to respond to at least one prior regimen were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally, QD in 28-day cycles until disease progression.

Reporting group title	Phase I, Stage 2: Cohort X - GDC-0032 6 mg QD

Reporting group description:

Participants with PIK3CA-mutant solid tumors that had progressed or failed to respond to at least one prior regimen were enrolled in this cohort to receive GDC-0032 6 mg tablets, orally QD in 28-day cycles until disease progression.

Reporting group title	Phase II: GDC-0032 6 mg QD + Fulv 500 mg

Reporting group description:

Postmenopausal participants with locally advanced or metastatic HER2-negative, hormone receptor-positive breast cancer who had not previously received fulvestrant were enrolled in this cohort to receive GDC-0032 6 mg tablets, orally, QD in 28-day cycles along with fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycles until disease progression.

Subject analysis set title	Phase I, Stage 1: GDC-0032 3 mg QD
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received GDC-0032 3 mg capsules, orally, once on Day 1 and then QD on Days 8 to 35 of Cycle 1 (Cycle 1 duration=35 days) and in subsequent 28-day cycles until disease progression.

Subject analysis set title	All Cohorts (Except T and T2)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants from Cohorts from Phase I Stage 1, Cohorts A, B, C, D, E, F, G, H, J, K, L, M, N, P, Q, R, S, X and Phase 2 were included in this analysis.

Subject analysis set title	Cohorts T and T2
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants from Cohorts T and T2 of Phase I, Stage 2 were included in this analysis.

Subject analysis set title	GDC-0032 Monotherapy
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants who received GDC-0032 as monotherapy in Stage 1, Stage 2 (Cohorts A, B, C, D, G, H, T,

T2, X) of Phase 1, and in Phase 2 were included in this analysis population.

Subject analysis set title	GDC-0032 + Letrozole
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants who received GDC-0032 in combination with letrozole in Stage 2 (Cohorts E, N, P, Q, R, S) were included in this analysis population.

Subject analysis set title	GDC-0032 + Fulvestrant
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants who received GDC-0032 in combination with fulvestrant in Stage 2 (Cohorts F, J, K, L, M) of Phase 1, and in Phase 2 were included in this analysis population.

Subject analysis set title	Cohort E
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants from Cohort E of Phase I, Stage 2 were included in this analysis.

Primary: Phase I Stage 1: Percentage of Participants with Dose-Limiting Toxicities (DLTs) as Assessed by National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.0 (NCI CTCAE v4.0)

End point title	Phase I Stage 1: Percentage of Participants with Dose-Limiting Toxicities (DLTs) as Assessed by National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.0 (NCI CTCAE v4.0)[1][2]

End point description:

A DLT is defined as any one of the following toxicities occurring within the DLT Assessment Window (Days 1-35 of Cycle 1 in Stage 1) assessed by the investigator: Grade ≥ 3 non-hematologic, non-hepatic organ system, non-metabolic (hyperglycemia and hyperlipidemia) toxicity, excluding alopecia of any grade, Grade 3 diarrhea, Grade 3 nausea or vomiting; Grade ≥ 4 thrombocytopenia; Grade ≥ 4 neutropenia lasting > 5 days or accompanied by fever; Fasting Grade ≥ 4 hyperglycemia or ≥ 3 hyperglycemia for ≥ 1 week; Grade ≥ 4 fasting hypercholesterolemia or triglyceridemia for ≥ 2 weeks; Grade ≥ 3 serum bilirubin or hepatic transaminase (ALT or AST); For participants abnormal at baseline: hepatic transaminase ≥ 7.5 × the upper limit of normal (ULN) or total bilirubin ≥ 5 × the ULN or 10 × the ULN or alkaline phosphatase ≥ 10 times the ULN. The safety-evaluable population was defined as all participants who received at least one dose of GDC-0032, letrozole, or fulvestrant.

End point type	Primary

End point timeframe:

Baseline up to 35 days of Cycle 1

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analyses have been specified 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: The data for this endpoint was collected for the participants in Phase 1 Stage 1 only

End point values	Phase I, Stage 1: GDC-0032 5 mg QD	Phase I, Stage 1: GDC-0032 8 mg QD	Phase I, Stage 1: GDC-0032 12 mg QD	Phase I, Stage 1: GDC-0032 16 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	10	11
Units: percentage of participants				
number (not applicable)	0.0	0.0	10.0	18.1

End point values	Phase I, Stage 1: GDC-0032 3			

	mg QD			
Subject group type	Subject analysis set			
Number of subjects analysed	6			
Units: percentage of participants				
number (not applicable)	0.0			

Statistical analyses

No statistical analyses for this end point

Primary: Phase I Stage 2 Cohorts E and F: Percentage of Participants with DLTs as Assessed by NCI CTCAE v4.0

End point title	Phase I Stage 2 Cohorts E and F: Percentage of Participants with DLTs as Assessed by NCI CTCAE v4.0[3][4]

End point description:

A DLT is defined as any one of the following toxicities occurring within the DLT Assessment Window (Days 1-28 of Cycle 1 in Stage 1) assessed by the investigator: Grade ≥ 3 non-hematologic, non-hepatic organ system, non-metabolic (hyperglycemia and hyperlipidemia) toxicity, excluding alopecia of any grade, Grade 3 diarrhea, Grade 3 nausea or vomiting; Grade ≥ 4 thrombocytopenia; Grade ≥ 4 neutropenia lasting > 5 days or accompanied by fever; Fasting Grade ≥ 4 hyperglycemia or ≥ 3 hyperglycemia for ≥ 1 week; Grade ≥ 4 fasting hypercholesterolemia or triglyceridemia for ≥ 2 weeks; Grade ≥ 3 serum bilirubin or hepatic transaminase (ALT or AST); For participants abnormal at baseline: hepatic transaminase ≥ 7.5 × ULN or total bilirubin ≥ 5 × the ULN or 10 × the ULN or alkaline phosphatase ≥ 10 times the ULN. The safety-evaluable population was defined as all participants who received at least one dose of GDC-0032, letrozole, or fulvestrant.

End point type	Primary

End point timeframe:

Baseline up to 28 days of Cycle 1

Notes:

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

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The data for this endpoint was collected for the participants in Phase 1 Stage 1 only

End point values	Phase I, Stage 2: Cohort E –GDC-0032 6 mg QD + Letro 2.5 mg QD	Phase I, Stage 2: Cohort E - GDC-0032 9 mg QD + Letro 2.5 mg QD	Phase I, Stage 2: Cohort F - GDC-0032 6 mg QD + Fulv 500 mg	Phase I, Stage 2: Cohort F - GDC-0032 9 mg QD + Fulv 500 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	8	21	6
Units: percentage of participants				
number (not applicable)	0.0	0.0	0.0	0.0

Statistical analyses

No statistical analyses for this end point

Primary: Phase I: AUC From Zero to tau (AUCtau) of GDC-0032

End point title	Phase I: AUC From Zero to tau (AUCtau) of GDC-0032[5][6]

End point description:

The concentrations are in micromole (µM), and the molecular weight of GDC-0032 is 460.53 g/mol. The safety-evaluable population was defined as all participants who received at least one dose of GDC-0032, letrozole, or fulvestrant. 'n' signifies number of participants analysed for this outcome measure at the specified timepoint.

End point type	Primary

End point timeframe:

Cycle 1, Day 1: Pre-dose (0-2 hours [hr]), 0.5, 1, 2, 3, 4, 8, 24, 48 and 72 hr; Day 15: Pre-dose (0-2 hr), 0.5, 1, 2, 3, 4, 8 and 24 hr

Notes:

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

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The data for this endpoint was collected for the participants in Phase 1 Stage 1 only

End point values	Phase I, Stage 1: GDC-0032 3 milligrams (mg) once daily (QD)	Phase I, Stage 1: GDC-0032 5 mg QD	Phase I, Stage 1: GDC-0032 8 mg QD	Phase I, Stage 1: GDC-0032 12 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	3	4	10
Units: micromolar per hour (µM*h)				
arithmetic mean (standard deviation)				
Day 1 (n=6, 3, 4, 10, 11)	0.441 (± 0.142)	0.547 (± 0.233)	1.34 (± 0.411)	1.8 (± 0.631)
Day 15 (n=6, 3, 3, 10, 9)	1.79 (± 0.962)	1.49 (± 0.786)	3.21 (± 1.636)	5.1 (± 2.035)

End point values	Phase I, Stage 1: GDC-0032 16 mg QD			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: micromolar per hour (µM*h)				
arithmetic mean (standard deviation)				
Day 1 (n=6, 3, 4, 10, 11)	2.26 (± 0.806)			
Day 15 (n=6, 3, 3, 10, 9)	8.1 (± 4.790)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase I: Maximum Observed Plasma Concentration (Cmax) of GDC-0032

End point title	Phase I: Maximum Observed Plasma Concentration (Cmax) of GDC-0032[7][8]

End point description:

The concentrations are in µM, and the molecular weight of GDC-0032 is 460.53 g/mol. The safety-evaluable population was defined as all participants who received at least one dose of GDC-0032,

letrozole, or fulvestrant. 'n' signifies number of participants analysed for this outcome measure at the specified timepoint.

End point type	Primary

End point timeframe:

Cycle 1, Day 1: Pre-dose (0-2 hours [hr]), 0.5, 1, 2, 3, 4, 8, 24, 48 and 72 hr; Day 15: Pre-dose (0-2 hr), 0.5, 1, 2, 3, 4, 8 and 24 hr

Notes:

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

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The data for this endpoint was collected for the participants in Phase 1 Stage 1 only

End point values	Phase I, Stage 1: GDC-0032 5 mg QD	Phase I, Stage 1: GDC-0032 8 mg QD	Phase I, Stage 1: GDC-0032 12 mg QD	Phase I, Stage 1: GDC-0032 16 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	10	11
Units: micromolar (µM)				
arithmetic mean (standard deviation)				
Day 1 (n=3, 4, 10, 11, 6)	0.0304 (± 0.0122)	0.0764 (± 0.0328)	0.127 (± 0.0529)	0.134 (± 0.0535)
Day 15 (n=3, 3, 10, 9, 6)	0.091 (± 0.048)	0.188 (± 0.119)	0.302 (± 0.100)	0.441 (± 0.251)

End point values	Phase I, Stage 1: GDC-0032 3 mg QD			
Subject group type	Subject analysis set			
Number of subjects analysed	6			
Units: micromolar (µM)				
arithmetic mean (standard deviation)				
Day 1 (n=3, 4, 10, 11, 6)	0.0256 (± 0.0094)			
Day 15 (n=3, 3, 10, 9, 6)	0.111 (± 0.072)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase I: Time to Reach Cmax (tmax) of GDC-0032

End point title	Phase I: Time to Reach Cmax (tmax) of GDC-0032[9][10]

End point description:

The safety-evaluable population was defined as all participants who received at least one dose of GDC-0032, letrozole, or fulvestrant.

End point type	Primary

End point timeframe:

Cycle 1, Day 1: Pre-dose (0-2 hours [hr]), 0.5, 1, 2, 3, 4, 8, 24, 48 and 72 hr; Day 15: Pre-dose (0-2 hr), 0.5, 1, 2, 3, 4, 8 and 24 hr

Notes:

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

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The data for this endpoint was collected for the participants in Phase 1 Stage 1 only

End point values	Phase I, Stage 1: GDC-0032 5 mg QD	Phase I, Stage 1: GDC-0032 8 mg QD	Phase I, Stage 1: GDC-0032 12 mg QD	Phase I, Stage 1: GDC-0032 16 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	10	11
Units: hours (hr)				
median (full range (min-max))	8 (3 to 8)	4 (2 to 4)	3 (1 to 8)	4 (2 to 24)

End point values	Phase I, Stage 1: GDC-0032 3 mg QD			
Subject group type	Subject analysis set			
Number of subjects analysed	6			
Units: hours (hr)				
median (full range (min-max))	4 (3 to 8)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase I: Terminal Half-life (t1/2) of GDC-0032

End point title	Phase I: Terminal Half-life (t1/2) of GDC-0032[11][12]

End point description:

The safety-evaluable population was defined as all participants who received at least one dose of GDC-0032, letrozole, or fulvestrant.

End point type	Primary

End point timeframe:

Cycle 1, Day 1: Pre-dose (0-2 hours [hr]), 0.5, 1, 2, 3, 4, 8, 24, 48 and 72 hr; Day 15: Pre-dose (0-2 hr), 0.5, 1, 2, 3, 4, 8 and 24 hr

Notes:

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

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The data for this endpoint was collected for the participants in Phase 1 Stage 1 only

End point values	Phase I, Stage 1: GDC-0032 5 mg QD	Phase I, Stage 1: GDC-0032 8 mg QD	Phase I, Stage 1: GDC-0032 12 mg QD	Phase I, Stage 1: GDC-0032 16 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	10	11
Units: hr				
arithmetic mean (standard deviation)	40 (± 21.0)	38.2 (± 9.1)	36.7 (± 8.3)	39.7 (± 8.0)

End point values	Phase I, Stage 1: GDC-0032 3 mg QD			
Subject group type	Subject analysis set			
Number of subjects analysed	6			
Units: hr				
arithmetic mean (standard deviation)	43.8 (± 11.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Across All Cohorts (Except Cohorts T and T2): Percentage of Participants With Best Overall Response (BOR) as Assessed Using Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1)

End point title	Across All Cohorts (Except Cohorts T and T2): Percentage of Participants With Best Overall Response (BOR) as Assessed Using Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1)[13]

End point description:

BOR was defined as having best objective response as complete response (CR) or partial response (PR), as assessed by RECIST v1.1. CR: disappearance of all target lesions. PR: At least a 30% decrease in the sum of diameters of all target lesions, taking as reference the baseline sum of diameters, in the absence of CR. The safety-evaluable population was defined as all participants who received at least one dose of GDC-0032, letrozole, or fulvestrant.

End point type	Primary

End point timeframe:

Baseline up to disease progression or death, whichever occurred first (up to a maximum of 67 months)

Notes:

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

End point values	All Cohorts (Except T and T2)			
Subject group type	Subject analysis set			
Number of subjects analysed	674			
Units: percentage of participants				
number (confidence interval 95%)	11.4 (9.1 to 14.1)			

Statistical analyses

No statistical analyses for this end point

Primary: Across All Cohorts (Except Cohorts T and T2): Duration of Objective Response (DOR) as Assessed Using RECIST v1.1

End point title	Across All Cohorts (Except Cohorts T and T2): Duration of Objective Response (DOR) as Assessed Using RECIST v1.1[14]

End point description:

DOR was defined as time from first occurrence of a documented objective response(OR) to progressive disease(PD) or death from any cause(whichever occurred first) as determined by investigator according to RECIST v1.1. OR=CR+PR. CR: disappearance of all target lesions. PR: At least a 30% decrease in sum of diameters of all target lesions, taking as reference the baseline sum of diameters, in absence of CR. PD: at least 20% increase in sum of diameters of target lesions, taking as reference the smallest sum of diameters on study (including baseline). In addition to relative increase of 20%, sum of diameters must also demonstrate an absolute increase of >/= 5 mm. Safety-evaluable population was defined as all participants who received at least one dose of GDC-0032, letrozole, or fulvestrant. '99999' signifies data was not estimable due to insufficient number of responders and insufficient amount of time passed to measure DOR. 'Number of subjects analyzed' signifies number of responders.

End point type	Primary

End point timeframe:

Baseline up to disease progression or death, whichever occurred first (up to a maximum of 67 months)

Notes:

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

End point values	All Cohorts (Except T and T2)			
Subject group type	Subject analysis set			
Number of subjects analysed	77			
Units: months				
median (confidence interval 95%)	99999 (-99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

Primary: Across All Cohorts (Except Cohorts T and T2): Progression-Free Survival (PFS) as Assessed Using RECIST v1.1

End point title	Across All Cohorts (Except Cohorts T and T2): Progression-Free Survival (PFS) as Assessed Using RECIST v1.1[15]

End point description:

PFS was defined as the time from randomization to the first occurrence of progressive disease (PD) or death from any cause (whichever occurred first), as determined by the investigator according to RECIST v1.1. PD: at least a 20% increase in the sum of diameters of target lesions, taking as reference the

smallest sum of diameters on study (including baseline). In addition to the relative increase of 20%, the sum of diameters must also demonstrate an absolute increase of >/= 5 millimeters (mm). The safety-

Primary: DOR in Cohort T and T2

End point title	DOR in Cohort T and T2[17]

End point description:

DOR in Cohort T was assessed using the 2007 Revised IWG Response Criteria in Malignant Lymphoma while in Cohort T2, it was assessed using the Modified Version of 2014 Lugano Response Criteria in Malignant Lymphoma. The safety-evaluable population was defined as all participants who received at least one dose of GDC-0032, letrozole, or fulvestrant. '99999' signifies data was not estimable due to insufficient number of responders and insufficient amount of time passed to measure DOR. 'Number of subjects analyzed' signifies the number of responders.

End point type	Primary

End point timeframe:

Baseline up to disease progression or death, whichever occurs first (up to a maximum of 46 months)

Notes:

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

End point values	Cohorts T and T2			
Subject group type	Subject analysis set			
Number of subjects analysed	4			
Units: months				
median (confidence interval 95%)	99999 (-99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

Primary: PFS in Cohort T and T2

End point title	PFS in Cohort T and T2[18]

End point description:

PFS in Cohort T was assessed using the 2007 Revised IWG Response Criteria in Malignant Lymphoma while in Cohort T2, it was assessed using the Modified Version of 2014 Lugano Response Criteria in Malignant Lymphoma. The safety-evaluable population was defined as all participants who received at least one dose of GDC-0032, letrozole, or fulvestrant. '99999' signifies upper limit of 95% confidence interval (CI) was not estimable due to low number of participants with events.

End point type	Primary

End point timeframe:

Baseline up to disease progression or death, whichever occurs first (up to a maximum of 46 months)

Notes:

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

End point values	Cohorts T and T2			
Subject group type	Subject analysis set			
Number of subjects analysed	20			
Units: months				
median (confidence interval 95%)	4.2 (1.8 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase I Stage 1: Percentage of Participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) by NCI CTCAE v4.0 grade

End point title	Phase I Stage 1: Percentage of Participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) by NCI CTCAE v4.0 grade[19]

End point description:

An AE is any unfavorable and unintended sign, symptom, or disease temporally associated with the use of an investigational medicinal product (IMP) or other protocol-imposed intervention, regardless of attribution. An SAE is any AE that is fatal, life-threatening, requires or prolongs inpatient hospitalization or results in persistent or significant disability/incapacity, a congenital anomaly/birth defect in a neonate/infant born to a mother exposed to the investigational product(s) or considered a significant medical event by the investigator. The safety-evaluable population was defined as all participants who received at least one dose of GDC-0032, letrozole, or fulvestrant.

End point type	Secondary

End point timeframe:

From first dose up to 30 days after the last dose of study drug or study discontinuation/termination (Up to a maximum of 16 months)

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The data for this endpoint was collected for the participants in Phase 1 Stage 1 only

End point values	Phase I, Stage 1: GDC-0032 5 mg QD	Phase I, Stage 1: GDC-0032 8 mg QD	Phase I, Stage 1: GDC-0032 12 mg QD	Phase I, Stage 1: GDC-0032 16 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	10	11
Units: percentage of participants				
number (not applicable)				
AEs	100.0	100.0	100.0	100.0
SAEs	0	50.0	40.0	81.8

End point values	Phase I, Stage 1: GDC-0032 3 mg QD			
Subject group type	Subject analysis set			
Number of subjects analysed	6			
Units: percentage of participants				
number (not applicable)				
AEs	100.0			
SAEs	16.7			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase I Stage 2: Percentage of Participants with AEs and SAEs by NCI CTCAE v4.0 grade

End point title	Phase I Stage 2: Percentage of Participants with AEs and SAEs by NCI CTCAE v4.0 grade[20]

End point description:

An AE is any unfavorable and unintended sign, symptom, or disease temporally associated with the use of an IMP or other protocol-imposed intervention, regardless of attribution. An SAE is any AE that is fatal, life-threatening, requires or prolongs inpatient hospitalization or results in persistent or significant disability/incapacity, a congenital anomaly/birth defect in a neonate/infant born to a mother exposed to the investigational product(s) or considered a significant medical event by the investigator. The safety-evaluable population was defined as all participants who received at least one dose of GDC-0032, letrozole, or fulvestrant.

End point type	Secondary

End point timeframe:

From first dose up to 30 days after the last dose of study drug or study discontinuation/termination (Up to a maximum of 67 months)

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The data for this endpoint was collected for the participants in Phase 1 Stage 1 only

End point values	Phase I, Stage 2: Cohort A - GDC-0032 9 mg QD	Phase I, Stage 2: Cohort B - GDC-0032 9 mg QD	Phase I, Stage 2: Cohort C - GDC-0032 9 mg QD + Mida 5 mg	Phase I, Stage 2: Cohort D - GDC-0032 9 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	13	10
Units: percentage of participants				
number (not applicable)				
AEs	100.0	100.0	92.3	100.0
SAEs	45.0	35.0	53.8	40.0

End point values	Phase I, Stage 2: Cohort E –GDC-0032 6 mg QD + Letro 2.5 mg QD	Phase I, Stage 2: Cohort E - GDC-0032 9 mg QD + Letro 2.5 mg QD	Phase I, Stage 2: Cohort F - GDC-0032 6 mg QD + Fulv 500 mg	Phase I, Stage 2: Cohort F - GDC-0032 9 mg QD + Fulv 500 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	8	21	6
Units: percentage of participants				
number (not applicable)				
AEs	100.0	87.5	100.0	100.0

SAEs	55.0	25.0	23.8	50.0

End point values	Phase I, Stage 2: Cohort G - GDC-0032 9 mg QD	Phase I, Stage 2: Cohort H - GDC-0032 6 mg QD	Phase I, Stage 2: Cohort J - GDC-0032 4 mg + Fulv 500 mg	Phase I, Stage 2: Cohort K - GDC-0032 4 mg + Fulv 500 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	35	20	20
Units: percentage of participants				
number (not applicable)				
AEs	100.0	100.0	95.0	95.0
SAEs	42.9	54.3	20.0	35.0

End point values	Phase I, Stage 2: Cohort L - GDC-0032 4 mg + Fulv 500 mg	Phase I, Stage 2: Cohort M - GDC-0032 2 mg QD + Fulv 500 mg	Phase I, Stage 2: Cohort N - GDC-0032 2 mg QD + Letro 2.5 mg QD	Phase I, Stage 2: Cohort P - GDC-0032 4 mg QD + Letro 2.5 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	20	27	28
Units: percentage of participants				
number (not applicable)				
AEs	100.0	100.0	100.0	96.4
SAEs	15.8	30.0	22.2	35.7

End point values	Phase I, Stage 2: Cohort Q - GDC-0032 4 mg + Letro 2.5 mg QD	Phase I, Stage 2: Cohort R - GDC-0032 4 mg + Letro 2.5 mg QD	Phase I, Stage 2: Cohort S - GDC-0032 4 mg + Letro 2.5 mg QD	Phase I, Stage 2: Cohort T - GDC-0032 4 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	20	10
Units: percentage of participants				
number (not applicable)				
AEs	100.0	100.0	95.0	100.0
SAEs	10.0	25.0	10.0	70.0

End point values	Phase I, Stage 2: Cohort T2 - GDC-0032 4 mg QD	Phase I, Stage 2: Cohort X - GDC-0032 4 mg QD	Phase I, Stage 2: Cohort X - GDC-0032 6 mg QD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	70	122	
Units: percentage of participants				
number (not applicable)				

AEs	100.0	100.0	99.2	
SAEs	40.0	57.1	51.6	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: Percentage of Participants with AEs and SAEs by NCI CTCAE v4.0 grade

End point title	Phase II: Percentage of Participants with AEs and SAEs by NCI CTCAE v4.0 grade[21]

End point description:

An AE is any unfavorable and unintended sign, symptom, or disease temporally associated with the use of an IMP or other protocol-imposed intervention, regardless of attribution. An SAE is any AE that is fatal, life-threatening, requires or prolongs inpatient hospitalization or results in persistent or significant disability/incapacity, a congenital anomaly/birth defect in a neonate/infant born to a mother exposed to the investigational product(s) or considered a significant medical event by the investigator. The safety-evaluable population was defined as all participants who received at least one dose of GDC-0032, letrozole, or fulvestrant.

End point type	Secondary

End point timeframe:

From first dose up to 30 days after the last dose of study drug or study discontinuation/termination (Up to a maximum of 54 months)

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The data for this endpoint was collected for the participants in Phase 1 Stage 1 only

End point values	Phase II: GDC-0032 6 mg QD + Fulv 500 mg			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: percentage of participants				
number (not applicable)				
AEs	100.0			
SAEs	31.7			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Clinical Relevant Shifts from Baseline in Laboratory Parameters

End point title	Percentage of Participants with Clinical Relevant Shifts from Baseline in Laboratory Parameters

End point description:

Laboratory parameters such as fasting glucose, absolute neutrophil count, hemoglobin, platelet count, lymphocytes, serum creatinine, aspartate aminotransferase (AST), alanine transaminase (ALT),

leukocytes, fasting triglycerides and fasting cholesterol were assessed. A clinical relevant shift from baseline was defined as a shift from Grade 0, 1, or 2 at baseline to Grade 3 or 4 post baseline. The safety-evaluable population was defined as all participants who received at least one dose of GDC-0032, letrozole, or fulvestrant.

End point type	Secondary

End point timeframe:

Baseline to a maximum of 67 months

End point values	GDC-0032 Monotherapy	GDC-0032 + Letrozole	GDC-0032 + Fulvestrant	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	365	143	166	
Units: percentage of participants				
number (not applicable)				
High Fasting Glucose	9.3	4.9	3.0	
Low Fasting Glucose	0	0	0	
Low Absolute Neutrophil Count	4.8	0	0.7	
High Hemoglobin	0	0	0	
Low Hemoglobin	5.2	0.7	1.2	
Low Platelet Count	1.5	0.7	0.6	
High Lymphocytes	0	0.9	0	
Low Lymphocytes	13.9	7.3	2.9	
High Serum Creatinine	0.9	0	2.5	
High AST	2.6	6.3	7.0	
High ALT	2.0	4.2	5.2	
High Leukocytes	0	0	0	
Low Leukocytes	2.1	1.4	0	
High Fasting Triglycerides	0.4	0.9	0.8	
High Fasting Cholesterol	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of GDC-0032 Under Fed Conditions

End point title	Cmax of GDC-0032 Under Fed Conditions[22]

End point description:

For dosing under fed conditions, participant fasted overnight for >/= 10 hours before the standard high-fat meal provided at the study site. Participants started the standard high fat meal 30 minutes prior to administration of GDC-0032. The safety-evaluable population was defined as all participants who received at least one dose of GDC-0032, letrozole, or fulvestrant.

End point type	Secondary

End point timeframe:

Cycle 1, Day 1: Pre-dose (0-2 hr), 1, 2, 3, 4, 8, and 24 hr; Day 8: Pre-dose (0-2 hr), 1, 2, 3, 4, 8 and 24 hr

Notes:

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

Justification: The data for this endpoint was collected for the participants in Phase 1 Stage 1 only

End point values	Phase I, Stage 2: Cohort A - GDC-0032 9 mg QD			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: µM				
arithmetic mean (standard deviation)	0.082 (± 0.038)			

Statistical analyses

No statistical analyses for this end point

Secondary: AUC of GDC-0032 Under Fed Conditions

End point title	AUC of GDC-0032 Under Fed Conditions[23]

End point description:

For dosing under fed conditions, participant fasted overnight for >/= 10 hours before the standard high-fat meal provided at the study site. Participants started the standard high fat meal 30 minutes prior to administration of GDC-0032. The safety-evaluable population was defined as all participants who received at least one dose of GDC-0032, letrozole, or fulvestrant.

End point type	Secondary

End point timeframe:

Cycle 1, Day 1: Pre-dose (0-2 hr), 1, 2, 3, 4, 8, and 24 hr; Day 8: Pre-dose (0-2 hr), 1, 2, 3, 4, 8 and 24 hr

Notes:

[23] - 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: The data for this endpoint was collected for the participants in Phase 1 Stage 1 only

End point values	Phase I, Stage 2: Cohort A - GDC-0032 9 mg QD			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: µM*hr				
arithmetic mean (standard deviation)	1.404 (± 0.656)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of GDC-0032 Under Fasted Conditions

End point title	Cmax of GDC-0032 Under Fasted Conditions[24]

End point description:	
Participants fasted overnight for at least 10 hours before dosing and 4 hours postdose. The safety-evaluable population was defined as all participants who received at least one dose of GDC-0032, letrozole, or fulvestrant.	
End point type	Secondary
End point timeframe:	
Cycle 1, Day 1: Pre-dose (0-2 hr), 1, 2, 3, 4, 8, and 24 hr; Day 8: Pre-dose (0-2 hr), 1, 2, 3, 4, 8 and 24 hr	
Notes:	
[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The data for this endpoint was collected for the participants in Phase 1 Stage 1 only	

End point values	Phase I, Stage 2: Cohort A - GDC-0032 9 mg QD			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: µM				
arithmetic mean (standard deviation)	0.085 (± 0.046)			

Statistical analyses

No statistical analyses for this end point

Secondary: AUC of GDC-0032 Under Fasted Conditions

End point title	AUC of GDC-0032 Under Fasted Conditions[25]
End point description:	
Participants fasted overnight for at least 10 hours before dosing and 4 hours postdose. The safety-evaluable population was defined as all participants who received at least one dose of GDC-0032, letrozole, or fulvestrant.	
End point type	Secondary
End point timeframe:	
Cycle 1, Day 1: Pre-dose (0-2 hr), 1, 2, 3, 4, 8, and 24 hr; Day 8: Pre-dose (0-2 hr), 1, 2, 3, 4, 8 and 24 hr	
Notes:	
[25] - 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: The data for this endpoint was collected for the participants in Phase 1 Stage 1 only	

End point values	Phase I, Stage 2: Cohort A - GDC-0032 9 mg QD			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: µM*hr				
arithmetic mean (standard deviation)	1.247 (± 0.911)			

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Ratio of Cmax for Midazolam plus GDC-0032 Relative to Cmax for Midazolam Alone

End point title	Geometric Mean Ratio of Cmax for Midazolam plus GDC-0032 Relative to Cmax for Midazolam Alone[26]

End point description:

The geometric mean ratio (90% CI) for midazolam+ GDC-0032 relative to midazolam alone was reported. The safety-evaluable population was defined as all participants who received at least one dose of GDC-0032, letrozole, or fulvestrant.

End point type	Secondary

End point timeframe:

Cycle 1, Day 1: Pre-dose (0-2 hr), 0.5, 1, 1.5, 2, 4, 8, 24 hr; Day 16: Pre-dose (0-2 hr), 0.5, 1, 1.5, 2, 3, 4, 8 and 24 hr

Notes:

[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The data for this endpoint was collected for the participants in Phase 1 Stage 1 only

End point values	Phase I, Stage 2: Cohort C - GDC-0032 9 mg QD + Mida 5 mg			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: geometric mean ratio				
number (confidence interval 90%)	0.98 (0.70 to 1.37)			

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Ratio of AUC for Midazolam plus GDC-0032 Relative to AUC for Midazolam Alone

End point title	Geometric Mean Ratio of AUC for Midazolam plus GDC-0032 Relative to AUC for Midazolam Alone[27]

End point description:

The geometric mean ratios (90% CIs) for midazolam + GDC-0032 relative to midazolam alone were reported. The safety-evaluable population was defined as all participants who received at least one dose of GDC-0032, letrozole, or fulvestrant.

End point type	Secondary

End point timeframe:

Cycle 1, Day 1: Pre-dose (0-2 hr), 0.5, 1, 1.5, 2, 4, 8, 24 hr; Day 16: Pre-dose (0-2 hr), 0.5, 1, 1.5, 2, 3, 4, 8 and 24 hr

Notes:

[27] - 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: The data for this endpoint was collected for the participants in Phase 1 Stage 1 only

End point values	Phase I, Stage 2: Cohort C - GDC-0032 9 mg QD + Mida 5 mg			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: geometric mean ratio				
number (confidence interval 90%)	1.04 (0.68 to 1.60)			

Statistical analyses

No statistical analyses for this end point

progression.

Reporting group title	Phase I, Stage 2: Cohort D - GDC-0032 9 mg QD

Reporting group description:

Participants with HER2- positive breast cancer were enrolled in this cohort to receive GDC 0032 9 mg capsules, orally, QD in 28-day cycles until disease progression.

Reporting group title	Phase I,Stage 2: Cohort E-GDC-0032 9mg QD+Letrozole 2.5mg QD

Reporting group description:

Postmenop ausal participants with hormone receptor positive breast cancer were enrolled in this cohort to receive GDC-0032 9 mg and letrozole 2.5 mg capsules, orally, QD in 28-day cycles until disease progression.

Reporting group title	Phase I,Stage 2:Cohort F-GDC-0032 6mg QD+Fulvestrant 500mg

Reporting group description:

Postmenop ausal participants with hormone receptor positive breast cancer were enrolled in this cohort to receive GDC-0032 6 mg capsules, orally, QD in 28-day cycles along with fulvestrant 500 mg, intramuscul arly (IM) on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28- day cycle until disease progression.

Reporting group title	Phase I, Stage 2: Cohort J-GDC-0032 4mg+Fulvestrant 500mg

Reporting group description:

Postmenopausal participants with hormone receptor positive breast cancer were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally, QD on Days 1 to 21 of each 28- day cycle along with fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28- day cycle until disease progression .

Reporting group title	Phase I,Stage 2:Cohort F-GDC-0032 9mg QD+Fulvestrant 500mg

Reporting group description:

Postmenopausal participants with hormone receptor positive breast cancer were enrolled in this cohort to receive GDC-0032 9 mg capsules, orally, QD in 28-day cycles along with fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28- day cycle until disease progression.

Reporting group title	Phase I, Stage 2: Cohort G - GDC-0032 9 mg QD

Reporting group description:

Participa nts with solid tumors with increase d PIK3CA copy number were enrolled in this cohort to receive GDC 0032 9 mg capsules , orally, QD in each 28- day cycle until disease progress ion

Reporting group title	Phase I, Stage 2: Cohort H - GDC-0032 6 mg QD

Reporting group description:

Participants with PIK3CA mutant solid tumors that are non breast and non colorect al cancer were enrolled in this cohort to receive GDC 0032 6 mg tablets, orally, QD on Days 1 to 21 of each 28- day cycle until disease progress ion.

Reporting group title	Phase I,Stage 2: Cohort L-GDC-0032 4mg + Fulvestrant 500mg

Reporting group description:

Postmenopausal participants with hormone receptor positive breast cancer were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally, QD on Days 1- 7 and 15-21 of each 28- day cycle along with fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28- day cycle until disease progression.

Reporting group title	Phase I,Stage 2: Cohort M-GDC-0032 2mg QD+Fulvestrant 500mg

Reporting group description:

Postmenopausal participants with hormone receptor positive breast cancer were enrolled in this cohort to receive GDC-0032 2 mg tablets, orally, QD in each 28- day cycle along with fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28- day cycle until disease progression.

Reporting group title	Phase I,Stage 2:Cohort N-GDC-0032 2mg QD+Letrozole 2.5mg QD

Reporting group description:

Postmenopausal participants with hormone receptor positive breast cancer were enrolled in this cohort to receive GDC-0032 2 mg tablets and letrozole 2.5 mg capsules, orally, QD in 28-day cycles until disease progression.

Reporting group title	Phase I,Stage 2:Cohort K-GDC-0032 4mg+Fulvestrant 500mg

Reporting group description:

Postmenopausal participants with hormone receptor positive breast cancer were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally, QD on Days 1- 5, 8-12, 15- 19, and 22- 26 of each 28-day cycle along with fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28- day cycle until disease progression.

Reporting group title	Phase I,Stage 2:Cohort R-GDC-0032 4mg+Letrozole 2.5mg QD

Reporting group description:

Postmenopausal participants with hormone receptor positive breast cancer were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally on Days 1-5, 8-12, 15- 19, and 22- 26 along with letrozole 2.5 mg capsules, orally, QD in 28-day cycles until disease progression.

Reporting group title	Phase I,Stage 2:Cohort P-GDC-0032 4mg QD+Letrozole 2.5mg QD

Reporting group description:

Postmenopausal participants with hormone receptor positive breast cancer were enrolled in this cohort to receive GDC-0032 4 mg tablets and letrozole 2.5 mg capsules, orally, QD in 28-day cycles until disease progression.

Reporting group title	Phase I,Stage 2:Cohort Q-GDC-0032 4mg+Letrozole 2.5mg QD

Reporting group description:

Postmenopausal participants with hormone receptor positive breast cancer were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally, QD on Days 1 to 21 along with letrozole 2.5 mg capsules, orally, QD in 28-day cycles until disease progression.

Reporting group title	Phase I,Stage 2:Cohort S-GDC-0032 4mg+Letrozole 2.5mg QD

Reporting group description:

Postmenopausal participants with hormone receptor-positive breast cancer were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally on Days 1-7 and 15-21 along with letrozole 2.5 mg capsules, orally, QD in 28-day cycles until disease progression.

Reporting group title	Phase I, Stage 2: Cohort T - GDC-0032 4 mg QD

Reporting group description:

Participants with non Hodgkin’s lymphoma that had progressed or had failed to respond to at least one prior regimen were enrolled in this cohort to receive GDC 0032 4 mg tablets, orally QD in 28-day cycles until disease progression.

Reporting group title	Phase I, Stage 2: Cohort T2 - GDC-0032 4 mg QD

Reporting group description:

Participants with DLBCL who had progressed or had failed to respond to at least one prior regimen were enrolled in this cohort to receive GDC 0032 4 mg tablets, orally, QD in 28-day cycles until disease progression.

Reporting group title	Phase I, Stage 2: Cohort X - GDC-0032 4 mg QD

Reporting group description:

Participants with PIK3CA mutant solid tumors that have progressed or failed to respond to at least one prior regimen were enrolled in this cohort to receive GDC-0032 4 mg tablets, orally, QD in 28- day cycles until disease progression.

Reporting group title	Phase II: GDC-0032 6 mg QD + Fulvestrant 500 mg

Reporting group description:

Postmenopausal participants with locally advanced or metastatic HER2-negative, hormone receptor-positive breast cancer who had not previously received fulvestrant were enrolled in this cohort to receive GDC 0032 6 mg tablets, orally, QD in 28-day cycles along with fulvestrant 500 mg, IM on Days 1 and 15 of Cycle 1 and thereafter on Day 1 of each 28-day cycles until disease progression.

Reporting group title	Phase I, Stage 2: Cohort X - GDC-0032 6 mg QD

Reporting group description:

Participants with PIK3CA mutant solid tumors that had progressed or failed to respond to at least one prior regimen were enrolled in this cohort to receive GDC-0032 6 mg tablets, orally QD in 28- day cycles until disease progression.

Serious adverse events	Phase I,Stage 1: GDC-0032 3 milligrams(mg) once daily(QD)	Phase I, Stage 1: GDC-0032 5 mg QD	Phase I, Stage 1: GDC-0032 16 mg QD
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	9 / 11 (81.82%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
MALIGNANT PLEURAL EFFUSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
HYPOTENSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTERIAL RUPTURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERTENSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SHOCK HAEMORRHAGIC			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENOUS THROMBOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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			
DEATH			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASTHENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FATIGUE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SOFT TISSUE INFLAMMATION			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUDDEN DEATH			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
HYPERSENSITIVITY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
FEMALE GENITAL TRACT FISTULA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVARIAN CYST RUPTURED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROSTATITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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			
PNEUMONIA ASPIRATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE RESPIRATORY DISTRESS SYNDROME			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANOXIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASTHMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATELECTASIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COUGH			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPNOEA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOPTYSIS			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOXIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARYNGEAL HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 INFILTRATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 TOXICITY			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY FAILURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
MENTAL STATUS CHANGES			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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			
AMYLASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 CREATININE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIPASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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			
FALL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

FEMUR FRACTURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RIB FRACTURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVERDOSE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TIBIA FRACTURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRACHEAL HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 PSEUDOANEURYSM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
CARDIAC ARREST			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 CONGESTIVE			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MITRAL VALVE DISEASE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERICARDIAL EFFUSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STRESS CARDIOMYOPATHY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR ARRHYTHMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR TACHYARRHYTHMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR TACHYCARDIA			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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			
CENTRAL NERVOUS SYSTEM LESION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEADACHE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEIZURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATAXIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRAIN OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIZZINESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENCEPHALOPATHY			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPILEPSY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FACIAL NERVE DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LETHARGY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
PAPILLOEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIARRHOEA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	2 / 11 (18.18%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL PERFORATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPHAGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTERITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROCOLITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 FISTULA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 NECROSIS			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JEJUNAL PERFORATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARGE INTESTINAL STENOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NARCOTIC BOWEL SYNDROME			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 COLITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PEPTIC ULCER PERFORATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STOMATITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBILEUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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			
CHOLELITHIASIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BILIARY OBSTRUCTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLANGITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLECYSTITIS			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC FAILURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JAUNDICE CHOLESTATIC			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PORTAL HYPERTENSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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			
EXFOLIATIVE RASH			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN OF SKIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH PRURITIC			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 FAILURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETERIC DILATATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETHRAL OBSTRUCTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACK PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

BONE PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FLANK PAIN			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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			
APPENDICITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIVERTICULITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELONEPHRITIS			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSEPSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 ABSCESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRAIN ABSCESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHEST WALL ABSCESS			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DENGUE FEVER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENDOCARDITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROBACTER INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROENTERITIS			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
KLEBSIELLA INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOCALISED INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAROTITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONITIS BACTERIAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PSEUDOMONAS INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 SYNCYTIAL VIRUS INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STAPHYLOCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 BACTERAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TOOTH ABSCESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VARICELLA ZOSTER VIRUS INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WOUND INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
DEHYDRATION			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DECREASED APPETITE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERCALCAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	2 / 11 (18.18%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERKALAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOKALAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPONATRAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOVOLAEMIA			

VXEMHFWV DIIHFWHG	H[SRVHG		
RFFXUUHQFHV FDXVDOO\ UHODWHG WR WUHDWPHQW DOO			
GHDWKV FDXVDOO\ UHODWHG WR WUHDWPHQW DOO			

Serious adverse events	3KDVH , 6WDJH *'& PJ 4'	3KDVH , 6WDJH *'& PJ 4'	3KDVH , 6WDJH &RKRUW % *'& PJ 4'
7RWDO VXEMHFWV DIIHFWHG E\ VHULRXV DGYHUVH HYHQWV			
VXEMHFWV DIIHFWHG	H[SRVHG		
QXPEHU RI GHDWKV DOO FDXVHV			
QXPEHU RI GHDWKV UHVXOWLQJ IURP DGYHUVH HYHQWV			
1HRSODVPV EHQLJQ PDOLJQDQW DQG XQVSHFLILHG LQFO F\VWV DQG SRO\SV			
0$/,*1$17 3/(85$/ ())86,21			
VXEMHFWV DIIHFWHG	H[SRVHG		
RFFXUUHQFHV FDXVDOO\ UHODWHG WR WUHDWPHQW DOO			
GHDWKV FDXVDOO\ UHODWHG WR WUHDWPHQW DOO			
9DVFXODU GLVRUGHUV			
+<327(16,21			
VXEMHFWV DIIHFWHG	H[SRVHG		
RFFXUUHQFHV FDXVDOO\ UHODWHG WR WUHDWPHQW DOO			
GHDWKV FDXVDOO\ UHODWHG WR WUHDWPHQW DOO			
$57(5,$/ 583785(			
VXEMHFWV DIIHFWHG	H[SRVHG		
RFFXUUHQFHV FDXVDOO\ UHODWHG WR WUHDWPHQW DOO			
GHDWKV FDXVDOO\ UHODWHG WR WUHDWPHQW DOO			
'((3 9(,1 7+520%26,6			
VXEMHFWV DIIHFWHG	H[SRVHG		
RFFXUUHQFHV FDXVDOO\ UHODWHG WR WUHDWPHQW DOO			
GHDWKV FDXVDOO\ UHODWHG WR WUHDWPHQW DOO			
+<3(57(16,21			
VXEMHFWV DIIHFWHG	H[SRVHG		
RFFXUUHQFHV FDXVDOO\ UHODWHG WR WUHDWPHQW DOO			
GHDWKV FDXVDOO\ UHODWHG WR WUHDWPHQW DOO			
/<03+2('(0$			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SHOCK HAEMORRHAGIC			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENOUS THROMBOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
DEATH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASTHENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FATIGUE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYREXIA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SOFT TISSUE INFLAMMATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUDDEN DEATH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
HYPERSENSITIVITY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
FEMALE GENITAL TRACT FISTULA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVARIAN CYST RUPTURED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROSTATITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
PNEUMONIA ASPIRATION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE RESPIRATORY DISTRESS SYNDROME			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANOXIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASTHMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATELECTASIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COUGH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPNOEA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOPTYSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOXIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARYNGEAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG INFILTRATION			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL EFFUSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY OEDEMA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY TOXICITY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY FAILURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Psychiatric disorders			
MENTAL STATUS CHANGES			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
AMYLASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIPASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural			

complications			
FALL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMUR FRACTURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RIB FRACTURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVERDOSE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TIBIA FRACTURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRACHEAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VASCULAR PSEUDOANEURYSM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
CARDIAC ARREST			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MITRAL VALVE DISEASE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERICARDIAL EFFUSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STRESS CARDIOMYOPATHY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR ARRHYTHMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR TACHYARRHYTHMIA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
CENTRAL NERVOUS SYSTEM LESION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEADACHE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEIZURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNCOPE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATAXIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRAIN OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIZZINESS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENCEPHALOPATHY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPILEPSY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FACIAL NERVE DISORDER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LETHARGY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			

PAPILLOEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
COLITIS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CONSTIPATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL VASCULAR MALFORMATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASCITES			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

COLITIS MICROSCOPIC			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CROHN'S DISEASE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIARRHOEA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL PERFORATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPHAGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTERITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROCOLITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL FISTULA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL NECROSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATEMESIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JEJUNAL PERFORATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARGE INTESTINAL STENOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NARCOTIC BOWEL SYNDROME			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIC COLITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PEPTIC ULCER PERFORATION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STOMATITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBILEUS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
CHOLELITHIASIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BILIARY OBSTRUCTION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLECYSTITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC FAILURE			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JAUNDICE CHOLESTATIC			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PORTAL HYPERTENSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
EXFOLIATIVE RASH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN OF SKIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH MACULO-PAPULAR			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH PRURITIC			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL FAILURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETERIC DILATATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETHRAL OBSTRUCTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

BACK PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BONE PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FLANK PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
APPENDICITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIVERTICULITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			

subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELONEPHRITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	2 / 20 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSEPSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL WALL ABSCESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRAIN ABSCESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHITIS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHEST WALL ABSCESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DENGUE FEVER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENDOCARDITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROBACTER INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRIC INFECTION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROENTERITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
KLEBSIELLA INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOCALISED INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAROTITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONITIS BACTERIAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PSEUDOMONAS INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY SYNCYTIAL VIRUS INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC SHOCK			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STAPHYLOCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STREPTOCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TOOTH ABSCESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VARICELLA ZOSTER VIRUS INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VASCULAR DEVICE INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WOUND INFECTION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
DEHYDRATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DECREASED APPETITE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERCALCAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERKALAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOKALAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPONATRAEMIA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOVOLAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase I, Stage 2: Cohort A - GDC-0032 9 mg QD	Phase I,Stage 2:Cohort C- GDC-0032 9 mg QD+Midazolam 5 mg	Phase I,Stage 2: Cohort E-GDC-0032 6mg QD+Letrozole 2.5mg QD
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 20 (45.00%)	7 / 13 (53.85%)	11 / 20 (55.00%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
MALIGNANT PLEURAL EFFUSION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
HYPOTENSION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTERIAL RUPTURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERTENSION			

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOEDEMA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SHOCK HAEMORRHAGIC			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENOUS THROMBOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
DEATH			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASTHENIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FATIGUE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN			

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYREXIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SOFT TISSUE INFLAMMATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUDDEN DEATH			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
HYPERSENSITIVITY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
FEMALE GENITAL TRACT FISTULA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVARIAN CYST RUPTURED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROSTATITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
PNEUMONIA ASPIRATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE RESPIRATORY DISTRESS SYNDROME			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANOXIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASTHMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATELECTASIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COUGH			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

DYSPNOEA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOPTYSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOXIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARYNGEAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY TOXICITY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY FAILURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
MENTAL STATUS CHANGES			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
AMYLASE INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIPASE INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural			

complications			
FALL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMUR FRACTURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RIB FRACTURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVERDOSE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TIBIA FRACTURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRACHEAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VASCULAR PSEUDOANEURYSM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
CARDIAC ARREST			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MITRAL VALVE DISEASE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERICARDIAL EFFUSION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STRESS CARDIOMYOPATHY			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR ARRHYTHMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR TACHYARRHYTHMIA			

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
CENTRAL NERVOUS SYSTEM LESION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEADACHE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEIZURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNCOPE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATAXIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRAIN OEDEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIZZINESS			

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENCEPHALOPATHY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPILEPSY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FACIAL NERVE DISORDER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LETHARGY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			

PAPILLOEDEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
COLITIS			
subjects affected / exposed	2 / 20 (10.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	2 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CONSTIPATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL VASCULAR MALFORMATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL PAIN			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASCITES			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

COLITIS MICROSCOPIC			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CROHN'S DISEASE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIARRHOEA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL PERFORATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPHAGIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTERITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROCOLITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL FISTULA			

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL NECROSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATEMESIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JEJUNAL PERFORATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARGE INTESTINAL STENOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NARCOTIC BOWEL SYNDROME			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIC COLITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PEPTIC ULCER PERFORATION			

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STOMATITIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBILEUS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
CHOLELITHIASIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BILIARY OBSTRUCTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLANGITIS			

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLECYSTITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC FAILURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JAUNDICE CHOLESTATIC			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PORTAL HYPERTENSION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
EXFOLIATIVE RASH			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN OF SKIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH MACULO-PAPULAR			

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH PRURITIC			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL FAILURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETERIC DILATATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETHRAL OBSTRUCTION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

BACK PAIN			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BONE PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FLANK PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
APPENDICITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIVERTICULITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			

subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHEST WALL ABSCESS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DENGUE FEVER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENDOCARDITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROBACTER INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRIC INFECTION			

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROENTERITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
KLEBSIELLA INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOCALISED INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAROTITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONITIS BACTERIAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PSEUDOMONAS INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY SYNCYTIAL VIRUS INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION			

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC SHOCK			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STAPHYLOCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STREPTOCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TOOTH ABSCESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VARICELLA ZOSTER VIRUS INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VASCULAR DEVICE INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WOUND INFECTION			

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
DEHYDRATION			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DECREASED APPETITE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERCALCAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERKALAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOKALAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPONATRAEMIA			

subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOVOLAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase I, Stage 2: Cohort D - GDC-0032 9 mg QD	Phase I,Stage 2: Cohort E-GDC-0032 9mg QD+Letrozole 2.5mg QD	Phase I,Stage 2:Cohort F-GDC-0032 6mg QD+Fulvestrant 500mg
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 10 (40.00%)	2 / 8 (25.00%)	5 / 21 (23.81%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
MALIGNANT PLEURAL EFFUSION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
HYPOTENSION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTERIAL RUPTURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERTENSION			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOEDEMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SHOCK HAEMORRHAGIC			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENOUS THROMBOSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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			
DEATH			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASTHENIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FATIGUE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SOFT TISSUE INFLAMMATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUDDEN DEATH			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
HYPERSENSITIVITY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
FEMALE GENITAL TRACT FISTULA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVARIAN CYST RUPTURED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROSTATITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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			
PNEUMONIA ASPIRATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE RESPIRATORY DISTRESS SYNDROME			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANOXIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASTHMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATELECTASIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COUGH			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

DYSPNOEA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOPTYSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOXIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARYNGEAL HAEMORRHAGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 INFILTRATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 / 8 (0.00%)	0 / 21 (0.00%)
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 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY OEDEMA			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 TOXICITY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY FAILURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
MENTAL STATUS CHANGES			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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			
AMYLASE INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 CREATININE INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIPASE INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
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			
FALL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMUR FRACTURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RIB FRACTURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVERDOSE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TIBIA FRACTURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRACHEAL HAEMORRHAGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 PSEUDOANEURYSM			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
CARDIAC ARREST			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 CONGESTIVE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MITRAL VALVE DISEASE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERICARDIAL EFFUSION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STRESS CARDIOMYOPATHY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR ARRHYTHMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR TACHYARRHYTHMIA			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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			
CENTRAL NERVOUS SYSTEM LESION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEADACHE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEIZURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATAXIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRAIN OEDEMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIZZINESS			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENCEPHALOPATHY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPILEPSY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FACIAL NERVE DISORDER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LETHARGY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			

PAPILLOEDEMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
COLITIS			
subjects affected / exposed	2 / 10 (20.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	3 / 3	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CONSTIPATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 VASCULAR MALFORMATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASCITES			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

COLITIS MICROSCOPIC			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CROHN'S DISEASE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 / 10 (0.00%)	1 / 8 (12.50%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	1 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL PERFORATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPHAGIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTERITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROCOLITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 FISTULA			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 NECROSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JEJUNAL PERFORATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARGE INTESTINAL STENOSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NARCOTIC BOWEL SYNDROME			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 COLITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PEPTIC ULCER PERFORATION			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STOMATITIS			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBILEUS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 / 8 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
CHOLELITHIASIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BILIARY OBSTRUCTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLANGITIS			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLECYSTITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC FAILURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JAUNDICE CHOLESTATIC			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PORTAL HYPERTENSION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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			
EXFOLIATIVE RASH			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN OF SKIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH MACULO-PAPULAR			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH PRURITIC			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL FAILURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETERIC DILATATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETHRAL OBSTRUCTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

BACK PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BONE PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FLANK PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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			
APPENDICITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIVERTICULITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			

subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	0 / 21 (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
PYELONEPHRITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSEPSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 ABSCESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRAIN ABSCESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHEST WALL ABSCESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DENGUE FEVER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENDOCARDITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROBACTER INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 INFECTION			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROENTERITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
KLEBSIELLA INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOCALISED INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAROTITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONITIS BACTERIAL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PSEUDOMONAS INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 SYNCYTIAL VIRUS INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STAPHYLOCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 BACTERAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TOOTH ABSCESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VARICELLA ZOSTER VIRUS INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 / 21 (0.00%)

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DECREASED APPETITE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERCALCAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERKALAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOKALAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
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 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOVOLAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase I, Stage 2: Cohort J-GDC-0032 4mg+Fulvestrant 500mg	Phase I,Stage 2:Cohort F-GDC-0032 9mg QD+Fulvestrant	Phase I, Stage 2: Cohort G - GDC-0032 9 mg QD
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 20 (20.00%)	3 / 6 (50.00%)	9 / 21 (42.86%)
number of deaths (all causes)	15	0	3
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
MALIGNANT PLEURAL EFFUSION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
HYPOTENSION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTERIAL RUPTURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERTENSION			

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOEDEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SHOCK HAEMORRHAGIC			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENOUS THROMBOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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			
DEATH			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
ASTHENIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FATIGUE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN			

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SOFT TISSUE INFLAMMATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUDDEN DEATH			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
HYPERSENSITIVITY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
FEMALE GENITAL TRACT FISTULA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVARIAN CYST RUPTURED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROSTATITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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			
PNEUMONIA ASPIRATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE RESPIRATORY DISTRESS SYNDROME			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANOXIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASTHMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATELECTASIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COUGH			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

DYSPNOEA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOPTYSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOXIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARYNGEAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 INFILTRATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	2 / 21 (9.52%)
occurrences causally related to treatment / all	1 / 1	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY OEDEMA			

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 TOXICITY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY FAILURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
MENTAL STATUS CHANGES			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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			
AMYLASE INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 CREATININE INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIPASE INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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			
FALL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMUR FRACTURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RIB FRACTURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVERDOSE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TIBIA FRACTURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRACHEAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 PSEUDOANEURYSM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
CARDIAC ARREST			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 CONGESTIVE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MITRAL VALVE DISEASE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERICARDIAL EFFUSION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STRESS CARDIOMYOPATHY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR ARRHYTHMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR TACHYARRHYTHMIA			

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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			
CENTRAL NERVOUS SYSTEM LESION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEADACHE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEIZURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATAXIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRAIN OEDEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIZZINESS			

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENCEPHALOPATHY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPILEPSY			
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 21 (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
FACIAL NERVE DISORDER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LETHARGY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			

PAPILLOEDEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
COLITIS			
subjects affected / exposed	1 / 20 (5.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CONSTIPATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 VASCULAR MALFORMATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASCITES			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

COLITIS MICROSCOPIC			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CROHN'S DISEASE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL PERFORATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0		

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 NECROSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (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
JEJUNAL PERFORATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARGE INTESTINAL STENOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NARCOTIC BOWEL SYNDROME			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 COLITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PEPTIC ULCER PERFORATION			

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STOMATITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBILEUS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 / 20 (0.00%)	1 / 6 (16.67%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
CHOLELITHIASIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BILIARY OBSTRUCTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLANGITIS			

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLECYSTITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC FAILURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JAUNDICE CHOLESTATIC			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PORTAL HYPERTENSION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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			
EXFOLIATIVE RASH			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN OF SKIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH MACULO-PAPULAR			

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH PRURITIC			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 FAILURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETERIC DILATATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETHRAL OBSTRUCTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

BACK PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BONE PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FLANK PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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			
APPENDICITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIVERTICULITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			

subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELONEPHRITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSEPSIS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 ABSCESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRAIN ABSCESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHEST WALL ABSCESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (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
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DENGUE FEVER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENDOCARDITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROBACTER INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 INFECTION			

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROENTERITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
KLEBSIELLA INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOCALISED INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAROTITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONITIS BACTERIAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PSEUDOMONAS INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 SYNCYTIAL VIRUS INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION			

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STAPHYLOCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
STREPTOCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TOOTH ABSCESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VARICELLA ZOSTER VIRUS INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
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 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WOUND INFECTION			

subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
DEHYDRATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DECREASED APPETITE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERCALCAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERKALAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOKALAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPONATRAEMIA			

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOVOLAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase I, Stage 2: Cohort H - GDC-0032 6 mg QD	Phase I,Stage 2: Cohort L-GDC-0032 4mg + Fulvestrant 500mg	Phase I,Stage 2: Cohort M-GDC-0032 2mg QD+Fulvestrant 500mg
Total subjects affected by serious adverse events			
subjects affected / exposed	19 / 35 (54.29%)	3 / 19 (15.79%)	6 / 20 (30.00%)
number of deaths (all causes)	27	11	17
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
MALIGNANT PLEURAL EFFUSION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
HYPOTENSION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTERIAL RUPTURE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEEP VEIN THROMBOSIS			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERTENSION			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOEDEMA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SHOCK HAEMORRHAGIC			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENOUS THROMBOSIS			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
DEATH			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASTHENIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FATIGUE			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUCOSAL INFLAMMATION			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYREXIA			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SOFT TISSUE INFLAMMATION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to		0 / 0	0 / 0

treatment / all
deaths causally related to

Respiratory, thoracic and mediastinal disorders			
PNEUMONIA ASPIRATION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY EMBOLISM			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE RESPIRATORY DISTRESS SYNDROME			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANOXIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASTHMA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATELECTASIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COUGH			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

DYSPNOEA			
subjects affected / exposed	2 / 35 (5.71%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOPTYSIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOXIA			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
LARYNGEAL HAEMORRHAGE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG INFILTRATION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL EFFUSION			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	2 / 35 (5.71%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY OEDEMA			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY TOXICITY			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY FAILURE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
MENTAL STATUS CHANGES			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
AMYLASE INCREASED			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIPASE INCREASED			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural			

complications			
FALL			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMUR FRACTURE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RIB FRACTURE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVERDOSE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TIBIA FRACTURE			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRACHEAL HAEMORRHAGE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VASCULAR PSEUDOANEURYSM			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
CARDIAC ARREST			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MITRAL VALVE DISEASE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERICARDIAL EFFUSION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STRESS CARDIOMYOPATHY			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR ARRHYTHMIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR TACHYARRHYTHMIA			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
CENTRAL NERVOUS SYSTEM LESION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEADACHE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEIZURE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNCOPE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATAXIA			
subjects affected / exposed	2 / 35 (5.71%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRAIN OEDEMA			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIZZINESS			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENCEPHALOPATHY			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPILEPSY			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FACIAL NERVE DISORDER			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LETHARGY			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			

PAPILLOEDEMA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
COLITIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CONSTIPATION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL VASCULAR MALFORMATION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL PAIN			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASCITES			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

COLITIS MICROSCOPIC			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CROHN'S DISEASE			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIARRHOEA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL PERFORATION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPHAGIA			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTERITIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROCOLITIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRITIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL FISTULA			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL NECROSIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATEMESIS			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JEJUNAL PERFORATION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARGE INTESTINAL STENOSIS			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NARCOTIC BOWEL SYNDROME			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIC COLITIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PEPTIC ULCER PERFORATION			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STOMATITIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBILEUS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			
subjects affected / exposed	2 / 35 (5.71%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
CHOLELITHIASIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BILIARY OBSTRUCTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLANGITIS			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLECYSTITIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC FAILURE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JAUNDICE CHOLESTATIC			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PORTAL HYPERTENSION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
EXFOLIATIVE RASH			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN OF SKIN			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH MACULO-PAPULAR			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH PRURITIC			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL FAILURE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETERIC DILATATION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETHRAL OBSTRUCTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

BACK PAIN			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BONE PAIN			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FLANK PAIN			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN IN EXTREMITY			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
APPENDICITIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIVERTICULITIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELONEPHRITIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSEPSIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL INFECTION			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL WALL ABSCESS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEMIA			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRAIN ABSCESS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHITIS			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHEST WALL ABSCESS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DENGUE FEVER			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENDOCARDITIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROBACTER INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRIC INFECTION			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROENTERITIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
KLEBSIELLA INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOCALISED INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAROTITIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONITIS BACTERIAL			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PSEUDOMONAS INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY SYNCYTIAL VIRUS INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC SHOCK			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STAPHYLOCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STREPTOCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TOOTH ABSCESS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VARICELLA ZOSTER VIRUS INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VASCULAR DEVICE INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WOUND INFECTION			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
DEHYDRATION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DECREASED APPETITE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERCALCAEMIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERGLYCAEMIA			
subjects affected / exposed	2 / 35 (5.71%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERKALAEMIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOKALAEMIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPONATRAEMIA			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOVOLAEMIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase I,Stage 2:Cohort N-GDC-0032 2mg QD+Letrozole 2.5mg	Phase I,Stage 2:Cohort K-GDC-0032 4mg+Fulvestrant	Phase I,Stage 2:Cohort R-GDC-0032 4mg+Letrozole 2.5mg QD
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 27 (22.22%)	7 / 20 (35.00%)	5 / 20 (25.00%)
number of deaths (all causes)	12	11	12
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
MALIGNANT PLEURAL EFFUSION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
HYPOTENSION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTERIAL RUPTURE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERTENSION			

subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOEDEMA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SHOCK HAEMORRHAGIC			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENOUS THROMBOSIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
DEATH			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASTHENIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FATIGUE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYREXIA			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SOFT TISSUE INFLAMMATION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUDDEN DEATH			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
HYPERSENSITIVITY			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
FEMALE GENITAL TRACT FISTULA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVARIAN CYST RUPTURED			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROSTATITIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
PNEUMONIA ASPIRATION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE RESPIRATORY DISTRESS SYNDROME			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANOXIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASTHMA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATELECTASIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COUGH			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

DYSPNOEA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOPTYSIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOXIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARYNGEAL HAEMORRHAGE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG INFILTRATION			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL EFFUSION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY OEDEMA			

subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY TOXICITY			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY FAILURE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
MENTAL STATUS CHANGES			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
AMYLASE INCREASED			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD CREATININE INCREASEDtreatment / all			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0

treat0 INCREASED

complications			
FALL			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMUR FRACTURE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RIB FRACTURE			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVERDOSE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TIBIA FRACTURE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRACHEAL HAEMORRHAGE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VASCULAR PSEUDOANEURYSM			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
CARDIAC ARREST			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

ATRIAL FIBRILLATION			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MITRAL VALVE DISEASE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERICARDIAL EFFUSION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STRESS CARDIOMYOPATHY			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR ARRHYTHMIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR TACHYARRHYTHMIA			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
CENTRAL NERVOUS SYSTEM LESION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEADACHE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEIZURE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNCOPE			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATAXIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRAIN OEDEMA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIZZINESS			

subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENCEPHALOPATHY			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPILEPSY			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FACIAL NERVE DISORDER			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LETHARGY			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			

PAPILLOEDEMA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
COLITIS			
subjects affected / exposed	1 / 27 (3.70%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	1 / 1	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CONSTIPATION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL VASCULAR MALFORMATION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL PAIN			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASCITES			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

COLITIS MICROSCOPIC			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CROHN'S DISEASE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIARRHOEA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL PERFORATION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPHAGIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTERITIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROCOLITIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRITIS			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL FISTULA			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL NECROSIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATEMESIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JEJUNAL PERFORATION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARGE INTESTINAL STENOSIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NARCOTIC BOWEL SYNDROME			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIC COLITIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PEPTIC ULCER PERFORATION			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STOMATITIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBILEUS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
CHOLELITHIASIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BILIARY OBSTRUCTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLANGITIS			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLECYSTITIS			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC FAILURE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JAUNDICE CHOLESTATIC			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PORTAL HYPERTENSION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
EXFOLIATIVE RASH			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN OF SKIN			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH MACULO-PAPULAR			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH PRURITIC			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL FAILURE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETERIC DILATATION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETHRAL OBSTRUCTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

BACK PAIN			
subjects affected / exposed	1 / 27 (3.70%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BONE PAIN			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FLANK PAIN			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN IN EXTREMITY			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
APPENDICITIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIVERTICULITIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELONEPHRITIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSEPSIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL WALL ABSCESS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEMIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRAIN ABSCESS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHITIS			

subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHEST WALL ABSCESS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DENGUE FEVER			
subjects affected / exposed		0 / 20 (0.00%)	0 / 20 (0.00%)

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROENTERITIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
KLEBSIELLA INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOCALISED INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAROTITIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONITIS BACTERIAL			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PSEUDOMONAS INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY SYNCYTIAL VIRUS INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC SHOCK			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STAPHYLOCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STREPTOCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TOOTH ABSCESS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VARICELLA ZOSTER VIRUS INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VASCULAR DEVICE INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WOUND INFECTION			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
DEHYDRATION			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DECREASED APPETITE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERCALCAEMIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERKALAEMIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOKALAEMIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPONATRAEMIA			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOVOLAEMIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase I,Stage 2:Cohort P-GDC-0032 4mg QD+Letrozole 2.5mg	Phase I,Stage 2:Cohort Q-GDC-0032 4mg+Letrozole 2.5mg QD	Phase I,Stage 2:Cohort S-GDC-0032 4mg+Letrozole 2.5mg QD
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 28 (35.71%)	2 / 20 (10.00%)	2 / 20 (10.00%)
number of deaths (all causes)	13	12	13
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
MALIGNANT PLEURAL EFFUSION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
HYPOTENSION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTERIAL RUPTURE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERTENSION			

subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOEDEMA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SHOCK HAEMORRHAGIC			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENOUS THROMBOSIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
DEATH			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASTHENIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FATIGUE			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUCOSAL INFLAMMATION			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYREXIA			
subjects affected / exposed	2 / 28 (7.14%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SOFT TISSUE INFLAMMATION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUDDEN DEATH			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
HYPERSENSITIVITY			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
FEMALE GENITAL TRACT FISTULA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVARIAN CYST RUPTURED			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROSTATITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
PNEUMONIA ASPIRATION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE RESPIRATORY DISTRESS SYNDROME			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANOXIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASTHMA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATELECTASIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COUGH			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

DYSPNOEA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOPTYSIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOXIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARYNGEAL HAEMORRHAGE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG INFILTRATION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL EFFUSION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY OEDEMA			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY TOXICITY			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY FAILURE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
MENTAL STATUS CHANGES			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
AMYLASE INCREASED			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIPASE INCREASED			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural			

complications			
FALL			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMUR FRACTURE			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RIB FRACTURE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVERDOSE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TIBIA FRACTURE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRACHEAL HAEMORRHAGE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VASCULAR PSEUDOANEURYSM			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
CARDIAC ARREST			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MITRAL VALVE DISEASE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERICARDIAL EFFUSION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STRESS CARDIOMYOPATHY			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR ARRHYTHMIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR TACHYARRHYTHMIA			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
CENTRAL NERVOUS SYSTEM LESION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEADACHE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEIZURE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNCOPE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATAXIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRAIN OEDEMA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIZZINESS			

subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all			

PAPILLOEDEMA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
COLITIS			
subjects affected / exposed	2 / 28 (7.14%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CONSTIPATION			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL VASCULAR MALFORMATION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL PAIN			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASCITES			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

COLITIS MICROSCOPIC			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CROHN'S DISEASE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIARRHOEA			
subjects affected / exposed	3 / 28 (10.71%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	4 / 4	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL PERFORATION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPHAGIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTERITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROCOLITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL FISTULA			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL NECROSIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATEMESIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JEJUNAL PERFORATION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARGE INTESTINAL STENOSIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NARCOTIC BOWEL SYNDROME			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIC COLITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PEPTIC ULCER PERFORATION			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STOMATITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBILEUS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
CHOLELITHIASIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BILIARY OBSTRUCTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLANGITIS			

subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLECYSTITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC FAILURE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JAUNDICE CHOLESTATIC			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PORTAL HYPERTENSION			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
EXFOLIATIVE RASH			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN OF SKIN			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH MACULO-PAPULAR			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH PRURITIC			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL FAILURE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETERIC DILATATION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETHRAL OBSTRUCTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

BACK PAIN			
subjects affected / exposed	2 / 28 (7.14%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BONE PAIN			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FLANK PAIN			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
APPENDICITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIVERTICULITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELONEPHRITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSEPSIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL WALL ABSCESS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEMIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRAIN ABSCESS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHITIS			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHEST WALL ABSCESS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DENGUE FEVER			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENDOCARDITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROBACTER INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRIC INFECTION			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROENTERITIS			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
KLEBSIELLA INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOCALISED INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAROTITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONITIS BACTERIAL			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PSEUDOMONAS INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY SYNCYTIAL VIRUS INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC SHOCK			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STAPHYLOCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STREPTOCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TOOTH ABSCESS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VARICELLA ZOSTER VIRUS INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VASCULAR DEVICE INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WOUND INFECTION			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
DEHYDRATION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DECREASED APPETITE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERCALCAEMIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERGLYCAEMIA			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERKALAEMIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOKALAEMIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPONATRAEMIA			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOEDEMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SHOCK HAEMORRHAGIC			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENOUS THROMBOSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
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			
DEATH			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASTHENIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FATIGUE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYREXIA			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SOFT TISSUE INFLAMMATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUDDEN DEATH			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
HYPERSENSITIVITY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
FEMALE GENITAL TRACT FISTULA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVARIAN CYST RUPTURED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROSTATITIS			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
PNEUMONIA ASPIRATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
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 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE RESPIRATORY DISTRESS SYNDROME			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANOXIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASTHMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATELECTASIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COUGH			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

DYSPNOEA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	3 / 70 (4.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOPTYSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOXIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARYNGEAL HAEMORRHAGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG INFILTRATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
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 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	2 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY OEDEMA			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
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 TOXICITY			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY FAILURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
MENTAL STATUS CHANGES			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
AMYLASE INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
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 CREATININE INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIPASE INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
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			
FALL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMUR FRACTURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RIB FRACTURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVERDOSE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TIBIA FRACTURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRACHEAL HAEMORRHAGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
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 PSEUDOANEURYSM			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
CARDIAC ARREST			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
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 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
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 CONGESTIVE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MITRAL VALVE DISEASE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERICARDIAL EFFUSION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STRESS CARDIOMYOPATHY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR ARRHYTHMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR TACHYARRHYTHMIA			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
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			
CENTRAL NERVOUS SYSTEM LESION			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 70 (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
HEADACHE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEIZURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNCOPE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATAXIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRAIN OEDEMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIZZINESS			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENCEPHALOPATHY			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 70 (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
EPILEPSY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FACIAL NERVE DISORDER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LETHARGY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
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 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEBRILE NEUTROPENIA			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 70 (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
NEUTROPENIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			

PAPILLOEDEMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
COLITIS			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CONSTIPATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL VASCULAR MALFORMATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
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 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASCITES			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

COLITIS MICROSCOPIC			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CROHN'S DISEASE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
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	3 / 10 (30.00%)	0 / 10 (0.00%)	3 / 70 (4.29%)
occurrences causally related to treatment / all	4 / 4	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL PERFORATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPHAGIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTERITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROCOLITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
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 FISTULA			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
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 NECROSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
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 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JEJUNAL PERFORATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARGE INTESTINAL STENOSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NARCOTIC BOWEL SYNDROME			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
		0 / 0	

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
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 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STOMATITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBILEUS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
CHOLELITHIASIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BILIARY OBSTRUCTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLANGITIS			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLECYSTITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC FAILURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JAUNDICE CHOLESTATIC			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PORTAL HYPERTENSION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
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			
EXFOLIATIVE RASH			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN OF SKIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH MACULO-PAPULAR			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH PRURITIC			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
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 / 10 (0.00%)	1 / 10 (10.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL FAILURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETERIC DILATATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETHRAL OBSTRUCTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
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			
ARTHRALGIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

BACK PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BONE PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FLANK PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
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			
APPENDICITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
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	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIVERTICULITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
PYELONEPHRITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSEPSIS			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
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 ABSCESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEMIA			
subjects affected / exposed	2 / 10 (20.00%)	0 / 10 (0.00%)	0 / 70 (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
BRAIN ABSCESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
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 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHEST WALL ABSCESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DENGUE FEVER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENDOCARDITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROBACTER INFECTION			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRIC INFECTION			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROENTERITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
KLEBSIELLA INFECTION			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 70 (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
LOCALISED INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAROTITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONITIS BACTERIAL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PSEUDOMONAS INFECTION			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY SYNCYTIAL VIRUS INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION			

subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
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	1 / 10 (10.00%)	1 / 10 (10.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STAPHYLOCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
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 BACTERAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TOOTH ABSCESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VARICELLA ZOSTER VIRUS INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
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 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WOUND INFECTION			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
DEHYDRATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DECREASED APPETITE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERCALCAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERKALAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOKALAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
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 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOVOLAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase II: GDC-0032 6 mg QD + Fulvestrant 500 mg	Phase I, Stage 2: Cohort X - GDC-0032 6 mg QD	
Total subjects affected by serious adverse events			
subjects affected / exposed	19 / 60 (31.67%)	63 / 122 (51.64%)	
number of deaths (all causes)	44	92	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
MALIGNANT PLEURAL EFFUSION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
HYPOTENSION			
subjects affected / exposed	0 / 60 (0.00%)	2 / 122 (1.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARTERIAL RUPTURE			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERTENSION			

subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LYMPHOEDEMA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SHOCK HAEMORRHAGIC			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
VENOUS THROMBOSIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
DEATH			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
ASTHENIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
FATIGUE			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PAIN			

subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PYREXIA			
subjects affected / exposed	0 / 60 (0.00%)	2 / 122 (1.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
SOFT TISSUE INFLAMMATION			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUDDEN DEATH			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Immune system disorders			
HYPERSENSITIVITY			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
FEMALE GENITAL TRACT FISTULA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
OVARIAN CYST RUPTURED			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PROSTATITIS			
subjects affected / exposed			

Respiratory, thoracic and mediastinal disorders			
PNEUMONIA ASPIRATION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY EMBOLISM			
subjects affected / exposed	1 / 60 (1.67%)	3 / 122 (2.46%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
ACUTE RESPIRATORY DISTRESS SYNDROME			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ANOXIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ASTHMA			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATELECTASIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COUGH			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

DYSPNOEA			
subjects affected / exposed	0 / 60 (0.00%)	5 / 122 (4.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMOPTYSIS			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
HYPOXIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LARYNGEAL HAEMORRHAGE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG INFILTRATION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PLEURAL EFFUSION			
subjects affected / exposed	1 / 60 (1.67%)	2 / 122 (1.64%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONITIS			
subjects affected / exposed	0 / 60 (0.00%)	2 / 122 (1.64%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMOTHORAX			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY OEDEMA			

subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY TOXICITY			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RESPIRATORY FAILURE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
MENTAL STATUS CHANGES			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
AMYLASE INCREASED			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LIPASE INCREASED			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural			

complications			
FALL			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
FEMUR FRACTURE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RIB FRACTURE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
OVERDOSE			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TIBIA FRACTURE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRACHEAL HAEMORRHAGE			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
VASCULAR PSEUDOANEURYSM			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
CARDIAC ARREST			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 60 (0.00%)	2 / 122 (1.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MITRAL VALVE DISEASE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERICARDIAL EFFUSION			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
STRESS CARDIOMYOPATHY			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VENTRICULAR ARRHYTHMIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VENTRICULAR TACHYARRHYTHMIA			

subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
CENTRAL NERVOUS SYSTEM LESION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEADACHE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SEIZURE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SYNCOPE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATAXIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRAIN OEDEMA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIZZINESS			

subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENCEPHALOPATHY			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
EPILEPSY			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
FACIAL NERVE DISORDER			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LETHARGY			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEUTROPENIA			
subjects affected / exposed	1 / 60 (1.67%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			

PAPILLOEDEMA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
COLITIS			
subjects affected / exposed	6 / 60 (10.00%)	7 / 122 (5.74%)	
occurrences causally related to treatment / all	6 / 6	7 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
CONSTIPATION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROINTESTINAL VASCULAR MALFORMATION			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABDOMINAL PAIN			
subjects affected / exposed	0 / 60 (0.00%)	5 / 122 (4.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
ASCITES			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

COLITIS MICROSCOPIC			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CROHN'S DISEASE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIARRHOEA			
subjects affected / exposed	1 / 60 (1.67%)	7 / 122 (5.74%)	
occurrences causally related to treatment / all	1 / 1	7 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
DUODENAL PERFORATION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DYSPHAGIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENTERITIS			
subjects affected / exposed	0 / 60 (0.00%)	2 / 122 (1.64%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENTEROCOLITIS			
subjects affected / exposed	1 / 60 (1.67%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTRITIS			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROINTESTINAL FISTULA			

subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROINTESTINAL NECROSIS			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMATEMESIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
JEJUNAL PERFORATION			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LARGE INTESTINAL STENOSIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NARCOTIC BOWEL SYNDROME			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NAUSEA			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEUTROPENIC COLITIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PEPTIC ULCER PERFORATION			

subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
STOMATITIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUBILEUS			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VOMITING			
subjects affected / exposed	0 / 60 (0.00%)	4 / 122 (3.28%)	
occurrences causally related to treatment / all	0 / 0	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
CHOLELITHIASIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BILIARY OBSTRUCTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHOLANGITIS			

subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHOLECYSTITIS			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATIC FAILURE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
JAUNDICE CHOLESTATIC			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PORTAL HYPERTENSION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
EXFOLIATIVE RASH			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PAIN OF SKIN			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RASH			
subjects affected / exposed	1 / 60 (1.67%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RASH MACULO-PAPULAR			

subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RASH PRURITIC			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL FAILURE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
URETERIC DILATATION			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
URETHRAL OBSTRUCTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

BACK PAIN			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BONE PAIN			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
FLANK PAIN			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PAIN IN EXTREMITY	NM		dMaths causallyted to

d ly related to

subjects affected / exposed	3 / 60 (5.00%)	5 / 122 (4.10%)	
occurrences causally related to treatment / all	0 / 5	1 / 7	
deaths causally related to treatment / all	0 / 1	0 / 1	
PYELONEPHRITIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
UROSEPSIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABDOMINAL INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	2 / 122 (1.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABDOMINAL WALL ABSCESS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BACTERAEMIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRAIN ABSCESS			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRONCHITIS			

subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHEST WALL ABSCESS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
DENGUE FEVER			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEVICE RELATED INFECTION			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
ENDOCARDITIS			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENTEROBACTER INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTRIC INFECTION			

subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROENTERITIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
KLEBSIELLA INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LOCALISED INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PAROTITIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERITONITIS BACTERIAL			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PSEUDOMONAS INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RESPIRATORY SYNCYTIAL VIRUS INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RESPIRATORY TRACT INFECTION			

subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SEPSIS			
subjects affected / exposed	1 / 60 (1.67%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
SEPTIC SHOCK			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
STAPHYLOCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
STREPTOCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TOOTH ABSCESS			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VARICELLA ZOSTER VIRUS INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VASCULAR DEVICE INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
WOUND INFECTION			

subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
DEHYDRATION			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DECREASED APPETITE			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERCALCAEMIA			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERGLYCAEMIA			
subjects affected / exposed	1 / 60 (1.67%)	4 / 122 (3.28%)	
occurrences causally related to treatment / all	0 / 1	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERKALAEMIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOKALAEMIA			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPONATRAEMIA			

subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOVOLAEMIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Phase I,Stage 1: GDC-0032 3 milligrams(mg) once daily(QD)	Phase I, Stage 1: GDC-0032 5 mg QD	Phase I, Stage 1: GDC-0032 16 mg QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	3 / 3 (100.00%)	11 / 11 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BENIGN NEOPLASM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
BRAIN NEOPLASM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HAEMANGIOMA OF SKIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
LIP NEOPLASM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PAPILLOMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
TUMOUR FISTULISATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
TUMOUR PAIN			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
EMBOLISM VENOUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
FLUSHING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HAEMATOMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HOT FLUSH			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HYPOTENSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
JUGULAR VEIN THROMBOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
LYMPHOEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
AXILLARY PAIN			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE ERYTHEMA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
CATHETER SITE INFLAMMATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE RASH			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
CHEST DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
CHEST PAIN			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
CHILLS			
subjects affected / exposed	0 / 6 (0.00%)	2 / 3 (66.67%)	0 / 11 (0.00%)
occurrences (all)	0	2	0
DEVICE RELATED THROMBOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
EARLY SATIETY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
FATIGUE			
subjects affected / exposed	2 / 6 (33.33%)	1 / 3 (33.33%)	8 / 11 (72.73%)
occurrences (all)	2	1	16
GAIT DISTURBANCE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
GENERAL PHYSICAL HEALTH			

DETERIORATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
GENERALISED OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE ERYTHEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE REACTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
MALAISE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	2
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	2 / 11 (18.18%)
occurrences (all)	0	0	3
OEDEMA PERIPHERAL			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SWELLING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PYREXIA			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	3 / 11 (27.27%)
occurrences (all)	1	1	3
XEROSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
CONTRAST MEDIA ALLERGY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HYPERSENSITIVITY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
SEASONAL ALLERGY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
BREAST DISCHARGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
BREAST MASS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
BREAST PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
DYSPAREUNIA			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
MENOPAUSAL SYMPTOMS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PELVIC PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PENILE HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
UTERINE PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
VAGINAL DISCHARGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
VAGINAL HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
VULVAL DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL BURNING SENSATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL DRYNESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL INFLAMMATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL PRURITUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Respiratory, thoracic and mediastinal disorders			
BRONCHOSPASM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
COUGH			
subjects affected / exposed	2 / 6 (33.33%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
DYSPHONIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
DYSPNOEA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
EPISTAXIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HAEMOPTYSIS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
HICCUPS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HYPOXIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
INCREASED UPPER AIRWAY SECRETION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
INTERSTITIAL LUNG DISEASE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
LOWER RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
LUNG CONSOLIDATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
NASAL CONGESTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
NASAL DRYNESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
PAINFUL RESPIRATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PARANASAL SINUS DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
PARANASAL SINUS HYPERSECRETION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PLEURAL EFFUSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PLEURITIC PAIN			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA ASPIRATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PNEUMONITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PRODUCTIVE COUGH			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PULMONARY OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
RHINITIS ALLERGIC			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
RHINORRHOEA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
SINUS CONGESTION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
SNEEZING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0

WHEEZING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
DEPRESSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
AGITATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
INSOMNIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
LIBIDO DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
MIXED ANXIETY AND DEPRESSIVE DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
MOOD ALTERED			
subjects affected / exposed	2 / 6 (33.33%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	3	0	0
MOOD SWINGS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Investigations			
WEIGHT DECREASED			
subjects affected / exposed	1 / 6 (16.67%)	2 / 3 (66.67%)	1 / 11 (9.09%)
occurrences (all)	1	3	1
ALANINE AMINOTRANSFERASE ABNORMAL			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	2 / 11 (18.18%)
occurrences (all)	0	1	2
AMYLASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ASPARTATE AMINOTRANSFERASE ABNORMAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	1 / 11 (9.09%)
occurrences (all)	0	2	1
BAND NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
BLOOD CALCIUM DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
BLOOD CHLORIDE DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATINE PHOSPHOKINASE INCREASED			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
BLOOD INSULIN INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
BLOOD MAGNESIUM DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
BLOOD MAGNESIUM INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
BLOOD PHOSPHORUS INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
BLOOD POTASSIUM DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
BLOOD TRIGLYCERIDES INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
BLOOD UREA INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ELECTROCARDIOGRAM QT PROLONGED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR INCREASED			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
INVESTIGATION ABNORMAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
LIPASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
LIVER FUNCTION TEST INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
LOW DENSITY LIPOPROTEIN INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PLATELET COUNT DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
STREPTOCOCCUS TEST POSITIVE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
TROPONIN INCREASED			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
WEIGHT INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
FALL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
ANIMAL BITE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
BURN ORAL CAVITY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
CHEST INJURY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
CONTUSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ESCHAR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
EYE INJURY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HIP FRACTURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
LIMB FRACTURE			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
LIMB INJURY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
POST PROCEDURAL HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PROCEDURAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
RADIATION SKIN INJURY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
RIB FRACTURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
SKIN ABRASION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
SKIN LACERATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
SPINAL COMPRESSION FRACTURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
SUNBURN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ULNA FRACTURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
ANGINA PECTORIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

ARRHYTHMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ATRIOVENTRICULAR BLOCK FIRST DEGREE			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
BRADYCARDIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
BUNDLE BRANCH BLOCK LEFT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
LEFT VENTRICULAR FAILURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
MITRAL VALVE INCOMPETENCE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PALPITATIONS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
SINUS TACHYCARDIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
TACHYCARDIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			

DIZZINESS			
subjects affected / exposed	0 / 6 (0.00%)	2 / 3 (66.67%)	4 / 11 (36.36%)
occurrences (all)	0	2	5
HEADACHE			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
BALANCE DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
CARPAL TUNNEL SYNDROME			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
DISTURBANCE IN ATTENTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
DYSAESTHESIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
DYSARTHRIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
DYSGEUSIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HYPERSOMNIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HYPOAESTHESIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
LETHARGY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
MEMORY IMPAIRMENT			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0

MIGRAINE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASTICITY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
NEURALGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
PARAESTHESIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PAROSMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PRESYNCOPE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
SCIATICA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
SEIZURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
SINUS HEADACHE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
SOMNOLENCE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

SYNCOPE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
TASTE DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
TREMOR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
ANAEMIA			

DEAFNESS UNILATERAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
EAR PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
EXCESSIVE CERUMEN PRODUCTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HYPOACUSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
MOTION SICKNESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
TINNITUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
VERTIGO			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
DIPLOPIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
DRY EYE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
EXOPHTHALMOS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
EYE IRRITATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
EYE PAIN			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
EYE SWELLING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
EYELID DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
EYELID PTOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
GLAUCOMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
LACRIMATION INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
OCULAR HYPERAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ORBITAL OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PERIORBITAL OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PERIORBITAL SWELLING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PHOTOPHOBIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PHOTOPSIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	5	0	0
SCLERAL HAEMORRHAGE			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
VISUAL IMPAIRMENT			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
VITREOUS FLOATERS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
DIARRHOEA			
subjects affected / exposed	1 / 6 (16.67%)	2 / 3 (66.67%)	9 / 11 (81.82%)
occurrences (all)	2	2	20
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL DISTENSION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
ABDOMINAL PAIN			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
ABDOMINAL WALL HAEMATOMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ANAL HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

ANORECTAL DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
APHTHOUS ULCER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ASCITES			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
CHAPPED LIPS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
CHEILITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
COLITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
CONSTIPATION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
DENTAL CARIES			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
DIVERTICULUM INTESTINAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
DRY MOUTH			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
DYSPEPSIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
DYSPHAGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

EPIGASTRIC DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ERUCTATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
FAECES DISCOLOURED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
FLATULENCE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
FREQUENT BOWEL MOVEMENTS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
GASTRIC ULCER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
GASTRITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
GINGIVAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
GLOSSITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
GLOSSODYNIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HAEMATOCHEZIA			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HAEMORRHOIDS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HYPERCHLORHYDRIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HYPOAESTHESIA ORAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
LARGE INTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
LIP PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
MESENTERIC ARTERY THROMBOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
MOUTH ULCERATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
NAUSEA			
subjects affected / exposed	3 / 6 (50.00%)	1 / 3 (33.33%)	7 / 11 (63.64%)
occurrences (all)	4	2	12
ODYNOPHAGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
OESOPHAGEAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
OESOPHAGITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ORAL DYSAESTHESIA			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ORAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
PARAESTHESIA ORAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PERIODONTAL DISEASE			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
PROCTALGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PROCTITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
RECTAL TENESMUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
RETCHING			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
STOMATITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	3 / 11 (27.27%)
occurrences (all)	0	0	4
TOOTHACHE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
VARICOSE VEINS SUBLINGUAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
VOMITING			

subjects affected / exposed	1 / 6 (16.67%)	2 / 3 (66.67%)	7 / 11 (63.64%)
occurrences (all)	1	2	10
Hepatobiliary disorders			
HEPATIC PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
RASH			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	3 / 11 (27.27%)
occurrences (all)	0	1	5
ALOPECIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
BLISTER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
COLD SWEAT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
DECUBITUS ULCER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
DERMATITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
DERMATITIS ALLERGIC			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
DERMATITIS EXFOLIATIVE GENERALISED			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
DRY SKIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
DYSHIDROTIC ECZEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ECCHYMOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
ECZEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ECZEMA ASTEATOTIC			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
ERYTHEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
EXFOLIATIVE RASH			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
HYPERHIDROSIS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
INGROWING NAIL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
NAIL DISCOLOURATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
NAIL DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
NAIL DYSTROPHY			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
NIGHT SWEATS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ONYCHOCLASIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ONYCHOLYSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ONYCHOMADESIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PAIN OF SKIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PAPULE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PHOTOSENSITIVITY REACTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PRURITUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PRURITUS ALLERGIC			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PSORIASIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
RASH MACULAR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
RASH PAPULAR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
RASH VESICULAR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ROSACEA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
SEBORRHOEIC DERMATITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
SKIN EXFOLIATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
SKIN FISSURES			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
SKIN HYPERPIGMENTATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

SKIN ULCER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
URTICARIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
AZOTAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
BLADDER DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
BLADDER SPASM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
CHROMATURIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
CYSTITIS NONINFECTIVE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
DYSURIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HAEMATURIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HYDRONEPHROSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
MICTURITION URGENCY			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
POLLAKIURIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
POLYURIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PROTEINURIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
RENAL FAILURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
URETERIC OBSTRUCTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
URETERIC STENOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
URINARY HESITATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
URINARY RETENTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
BACK PAIN			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
ARTHRALGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
ARTHRITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
BONE PAIN			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
FLANK PAIN			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	3	0	0
GROIN PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
INTERVERTEBRAL DISC PROTRUSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
JOINT RANGE OF MOTION DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
JOINT SWELLING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
MUSCLE DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	2 / 11 (18.18%)
occurrences (all)	2	0	2
MUSCLE TIGHTNESS			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL STIFFNESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
MYALGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
NECK PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
OSTEONECROSIS OF JAW			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	3 / 11 (27.27%)
occurrences (all)	0	0	3
PAIN IN JAW			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
SPINAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

BRONCHITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
NASOPHARYNGITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	2	0	1
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
BACTERAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
CANDIDA INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
CELLULITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVITIS VIRAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
CYSTITIS			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
CYTOMEGALOVIRUS INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
DIENTAMOEBA INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
EAR INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ERYTHEMA INDURATUM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
FUNGAL INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
FUNGAL SKIN INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
FURUNCLE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
GASTROINTESTINAL VIRAL INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
GINGIVITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
GROIN ABSCESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

HERPES ZOSTER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HORDEOLUM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
LARYNGITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
LOCALISED INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
MASTITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
MUCOSAL INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
NAIL INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ORAL HERPES			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PARONYCHIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	2 / 11 (18.18%)
occurrences (all)	1	0	2
PURULENT DISCHARGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
PYELONEPHRITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY SYNCYTIAL VIRUS INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
SINUSITIS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
SKIN CANDIDA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
SKIN INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
STOMA SITE INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
TOOTH ABSCESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
TOOTH INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

URINARY TRACT INFECTION BACTERIAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
VAGINAL INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
VARICELLA ZOSTER VIRUS INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
VIRAL INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
VULVOVAGINAL MYCOTIC INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	1 / 6 (16.67%)	2 / 3 (66.67%)	7 / 11 (63.64%)
occurrences (all)	1	2	9
DEHYDRATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	4 / 11 (36.36%)
occurrences (all)	0	0	6
ELECTROLYTE IMBALANCE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
FAILURE TO THRIVE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
FLUID OVERLOAD			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

GLUCOSE TOLERANCE IMPAIRED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HYPERCALCAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HYPERCHOLESTEROLAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	8 / 11 (72.73%)
occurrences (all)	0	0	22
HYPERKALAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HYPERMAGNESAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HYPERPHOSPHATAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HYPERTRIGLYCERIDAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
HYPERURICAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HYPOCALCAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

HYPOKALAEMIA			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	4 / 11 (36.36%)
occurrences (all)	1	1	4
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
HYPONATRAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	3 / 11 (27.27%)
occurrences (all)	0	0	3
HYPOPHAGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
HYPOVOLAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
LACTIC ACIDOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
MALNUTRITION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
POLYDIPSIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase I, Stage 1: GDC-0032 8 mg QD	Phase I, Stage 1: GDC-0032 12 mg QD	Phase I, Stage 2: Cohort B - GDC-0032 9 mg QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	10 / 10 (100.00%)	19 / 20 (95.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BENIGN NEOPLASM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BRAIN NEOPLASM			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HAEMANGIOMA OF SKIN			
subjects affected / exposed			0 / 20 (0.00%)

0 / 20 (0.00%)

HYPOTENSION			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
JUGULAR VEIN THROMBOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LYMPHOEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	3 / 20 (15.00%)
occurrences (all)	0	0	6
AXILLARY PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE ERYTHEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE INFLAMMATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE RASH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CHEST DISCOMFORT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CHEST PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CHILLS			

subjects affected / exposed	1 / 4 (25.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	1	2	0
DEVICE RELATED THROMBOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EARLY SATIETY			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
FATIGUE			
subjects affected / exposed	2 / 4 (50.00%)	6 / 10 (60.00%)	5 / 20 (25.00%)
occurrences (all)	3	8	7
GAIT DISTURBANCE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
GENERALISED OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE ERYTHEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE REACTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MALAISE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 4 (0.00%)	2 / 10 (20.00%)	3 / 20 (15.00%)
occurrences (all)	0	4	5
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences (all)	0	2	1
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	3 / 20 (15.00%)
occurrences (all)	0	2	3
PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SWELLING			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
PYREXIA			
subjects affected / exposed	1 / 4 (25.00%)	5 / 10 (50.00%)	2 / 20 (10.00%)
occurrences (all)	1	5	2
XEROSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
CONTRAST MEDIA ALLERGY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERSENSITIVITY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
SEASONAL ALLERGY			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
BREAST DISCHARGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BREAST MASS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BREAST PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
DYSPAREUNIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MENOPAUSAL SYMPTOMS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PELVIC PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PENILE HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
UTERINE PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
VAGINAL DISCHARGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	2
VAGINAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VULVAL DISORDER			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL BURNING SENSATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL DRYNESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL INFLAMMATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL PRURITUS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
BRONCHOSPASM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
COUGH			
subjects affected / exposed	1 / 4 (25.00%)	3 / 10 (30.00%)	1 / 20 (5.00%)
occurrences (all)	1	5	1
DYSPHONIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DYSPNOEA			
subjects affected / exposed	1 / 4 (25.00%)	3 / 10 (30.00%)	4 / 20 (20.00%)
occurrences (all)	1	3	11
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 4 (0.00%)	2 / 10 (20.00%)	1 / 20 (5.00%)
occurrences (all)	0	3	1
EPISTAXIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HAEMOPTYSIS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HICCUPS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOXIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INCREASED UPPER AIRWAY SECRETION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INTERSTITIAL LUNG DISEASE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LARYNGEAL INFLAMMATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LOWER RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LUNG CONSOLIDATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NASAL CONGESTION			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
NASAL DRYNESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL DISCOMFORT			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
OROPHARYNGEAL PAIN			

subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
PAINFUL RESPIRATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PARANASAL SINUS DISCOMFORT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PARANASAL SINUS HYPERSECRETION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PLEURAL EFFUSION			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
PLEURITIC PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA ASPIRATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PNEUMONITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PULMONARY OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RHINITIS ALLERGIC			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

RHINORRHOEA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
SINUS CONGESTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SNEEZING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
UPPER RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
WHEEZING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
DEPRESSION			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
AGITATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INSOMNIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
LIBIDO DECREASED			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MIXED ANXIETY AND DEPRESSIVE DISORDER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MOOD ALTERED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MOOD SWINGS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Investigations			
WEIGHT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	4 / 20 (20.00%)
occurrences (all)	0	0	4
ALANINE AMINOTRANSFERASE ABNORMAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences (all)	0	2	1
AMYLASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
ASPARTATE AMINOTRANSFERASE ABNORMAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
BAND NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	3
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD CALCIUM DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD CHLORIDE DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	2 / 10 (20.00%)	0 / 20 (0.00%)
occurrences (all)	0	5	0
BLOOD INSULIN INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
BLOOD MAGNESIUM DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
BLOOD MAGNESIUM INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD PHOSPHORUS INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD POTASSIUM DECREASED			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD TRIGLYCERIDES INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD UREA INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ELECTROCARDIOGRAM QT PROLONGED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INVESTIGATION ABNORMAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LIPASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1

LIPV AUNTOON AT

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	5
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PLATELET COUNT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	3
STREPTOCOCCUS TEST POSITIVE			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TROPONIN INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
WEIGHT INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
FALL			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
ANIMAL BITE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
BURN ORAL CAVITY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CHEST INJURY			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CONTUSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ESCHAR			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EYE INJURY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HIP FRACTURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LIMB FRACTURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LIMB INJURY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
POST PROCEDURAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
PROCEDURAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
RADIATION SKIN INJURY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RIB FRACTURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN ABRASION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN LACERATION			

subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
SPINAL COMPRESSION FRACTURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SUNBURN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
ULNA FRACTURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
ANGINA PECTORIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ARRHYTHMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ATRIAL FIBRILLATION			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
ATRIOVENTRICULAR BLOCK FIRST DEGREE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BRADYCARDIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BUNDLE BRANCH BLOCK LEFT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LEFT VENTRICULAR FAILURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MITRAL VALVE INCOMPETENCE			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PALPITATIONS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SINUS TACHYCARDIA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TACHYCARDIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	1 / 4 (25.00%)	2 / 10 (20.00%)	3 / 20 (15.00%)
occurrences (all)	2	2	3
HEADACHE			
subjects affected / exposed	0 / 4 (0.00%)	4 / 10 (40.00%)	2 / 20 (10.00%)
occurrences (all)	0	6	3
BALANCE DISORDER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CARPAL TUNNEL SYNDROME			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DISTURBANCE IN ATTENTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DYSAESTHESIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DYSARTHRIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

DYSGEUSIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	3 / 20 (15.00%)
occurrences (all)	0	1	4
HYPERSOMNIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
HYPOAESTHESIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
LETHARGY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MEMORY IMPAIRMENT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MIGRAINE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASTICITY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NEURALGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
PARAESTHESIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
PAROSMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 4 (0.00%)	2 / 10 (20.00%)	1 / 20 (5.00%)
occurrences (all)	0	2	1

PRESYNCOPE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SCIATICA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SEIZURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SINUS HEADACHE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SOMNOLENCE			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
SYNCOPE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TASTE DISORDER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TREMOR			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	1 / 4 (25.00%)	2 / 10 (20.00%)	4 / 20 (20.00%)
occurrences (all)	1	2	12
DISSEMINATED INTRAVASCULAR COAGULATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
IRON DEFICIENCY ANAEMIA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LEUKOPENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LYMPHOPENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NEUTROPENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	4
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
DEAFNESS UNILATERAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EAR PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EXCESSIVE CERUMEN PRODUCTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOACUSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MOTION SICKNESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TINNITUS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VERTIGO			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Eye disorders			
DIPLOPIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DRY EYE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
EXOPHTHALMOS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EYE IRRITATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EYE PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EYE SWELLING			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
EYELID DISORDER			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
EYELID PTOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GLAUCOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LACRIMATION INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
OCULAR HYPERAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
ORBITAL OEDEMA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PERIORBITAL OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PERIORBITAL SWELLING			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
PHOTOPHOBIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PHOTOPSIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SCLERAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
VISUAL IMPAIRMENT			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
VITREOUS FLOATERS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
DIARRHOEA			
subjects affected / exposed	1 / 4 (25.00%)	7 / 10 (70.00%)	16 / 20 (80.00%)
occurrences (all)	1	14	31
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 4 (0.00%)	2 / 10 (20.00%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0

ABDOMINAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	2 / 20 (10.00%)
occurrences (all)	0	1	2
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	3 / 20 (15.00%)
occurrences (all)	0	1	5
ABDOMINAL WALL HAEMATOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ANAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ANORECTAL DISCOMFORT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
APHTHOUS ULCER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ASCITES			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences (all)	0	2	1
CHAPPED LIPS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CHEILITIS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
COLITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CONSTIPATION			
subjects affected / exposed	0 / 4 (0.00%)	2 / 10 (20.00%)	1 / 20 (5.00%)
occurrences (all)	0	2	1

DENTAL CARIES			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DIVERTICULUM INTESTINAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DRY MOUTH			
subjects affected / exposed	0 / 4 (0.00%)	2 / 10 (20.00%)	2 / 20 (10.00%)
occurrences (all)	0	2	2
DYSPEPSIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
DYSPHAGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	3 / 20 (15.00%)
occurrences (all)	0	0	3
EPIGASTRIC DISCOMFORT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ERUCTATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FAECES DISCOLOURED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FLATULENCE			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
FREQUENT BOWEL MOVEMENTS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GASTRIC ULCER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GASTRITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
GINGIVAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GLOSSITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GLOSSODYNIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HAEMATOCHEZIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HAEMORRHOIDS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERCHLORHYDRIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOAESTHESIA ORAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LARGE INTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LIP PAIN			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
MESENTERIC ARTERY THROMBOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MOUTH ULCERATION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
NAUSEA			
subjects affected / exposed	1 / 4 (25.00%)	9 / 10 (90.00%)	7 / 20 (35.00%)
occurrences (all)	1	12	8
ODYNOPHAGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
OESOPHAGEAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
OESOPHAGITIS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
ORAL DYSAESTHESIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ORAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
PARAESTHESIA ORAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PERIODONTAL DISEASE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PROCTALGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
PROCTITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
RECTAL TENESMUS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RETCHING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	0 / 4 (0.00%)	4 / 10 (40.00%)	2 / 20 (10.00%)
occurrences (all)	0	5	3
TOOTHACHE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VARICOSE VEINS SUBLINGUAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VOMITING			
subjects affected / exposed	0 / 4 (0.00%)	5 / 10 (50.00%)	4 / 20 (20.00%)
occurrences (all)	0	6	6
Hepatobiliary disorders			
HEPATIC PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
RASH			
subjects affected / exposed	0 / 4 (0.00%)	3 / 10 (30.00%)	5 / 20 (25.00%)
occurrences (all)	0	11	8
ALOPECIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
BLISTER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
COLD SWEAT			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DECUBITUS ULCER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DERMATITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DERMATITIS ALLERGIC			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
DERMATITIS EXFOLIATIVE GENERALISED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DRY SKIN			
subjects affected / exposed	0 / 4 (0.00%)	2 / 10 (20.00%)	3 / 20 (15.00%)
occurrences (all)	0	4	3
DYSHIDROTIC ECZEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ECCHYMOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ECZEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ECZEMA ASTEATOTIC			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ERYTHEMA			
subjects affected / exposed	1 / 4 (25.00%)	2 / 10 (20.00%)	2 / 20 (10.00%)
occurrences (all)	1	6	2

EXFOLIATIVE RASH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INGROWING NAIL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NAIL DISCOLOURATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NAIL DISORDER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NAIL DYSTROPHY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NIGHT SWEATS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ONYCHOCLASIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ONYCHOLYSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ONYCHOMADESIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PAIN OF SKIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PAPULE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PHOTOSENSITIVITY REACTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PRURITUS			
subjects affected / exposed	0 / 4 (0.00%)	3 / 10 (30.00%)	2 / 20 (10.00%)
occurrences (all)	0	4	3
PRURITUS ALLERGIC			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
PSORIASIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RASH MACULAR			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences (all)	0	1	3
RASH PAPULAR			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
RASH VESICULAR			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ROSACEA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SEBORRHOEIC DERMATITIS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN EXFOLIATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN FISSURES			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN HYPERPIGMENTATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN PLAQUE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN TIGHTNESS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
SKIN ULCER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URTICARIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 4 (0.00%)	2 / 10 (20.00%)	0 / 20 (0.00%)
occurrences (all)	0	3	0
AZOTAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	6	0
BLADDER DISCOMFORT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLADDER SPASM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

CHROMATURIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CYSTITIS NONINFECTIVE			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
DYSURIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
HAEMATURIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYDRONEPHROSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MICTURITION URGENCY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
POLLAKIURIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
POLYURIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PROTEINURIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RENAL FAILURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URETERIC OBSTRUCTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URETERIC STENOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

URINARY HESITATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URINARY RETENTION			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
ARTHRALGIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	3 / 20 (15.00%)
occurrences (all)	0	1	4
ARTHRITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BONE PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FLANK PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
GROIN PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INTERVERTEBRAL DISC PROTRUSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
JOINT RANGE OF MOTION DECREASED			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
JOINT SWELLING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUSCLE DISORDER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
MUSCLE TIGHTNESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
MUSCULOSKELETAL DISCOMFORT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL STIFFNESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MYALGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NECK PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
OSTEONECROSIS OF JAW			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
PAIN IN JAW			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SPINAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
NASOPHARYNGITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 4 (25.00%)	2 / 10 (20.00%)	1 / 20 (5.00%)
occurrences (all)	1	2	1
BACTERAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CANDIDA INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CELLULITIS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVITIS VIRAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GASTROINTESTINAL VIRAL INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GINGIVITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GROIN ABSCESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HERPES ZOSTER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HORDEOLUM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LARYNGITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
LOCALISED INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MASTITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUCOSAL INFECTION			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
NAIL INFECTION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
ORAL HERPES			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PARONYCHIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
PURULENT DISCHARGE			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
PYELONEPHRITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY SYNCYTIAL VIRUS INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SINUSITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
SKIN CANDIDA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

SKIN INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
STOMA SITE INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
TOOTH ABSCESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TOOTH INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT INFECTION BACTERIAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
VAGINAL INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VARICELLA ZOSTER VIRUS INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VIRAL INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL MYCOTIC INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	2 / 4 (50.00%)	6 / 10 (60.00%)	5 / 20 (25.00%)
occurrences (all)	3	7	6

DEHYDRATION			
subjects affected / exposed	1 / 4 (25.00%)	2 / 10 (20.00%)	3 / 20 (15.00%)
occurrences (all)	1	3	3
ELECTROLYTE IMBALANCE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FAILURE TO THRIVE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FLUID OVERLOAD			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GLUCOSE TOLERANCE IMPAIRED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
HYPERCALCAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERCHOLESTEROLAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERGLYCAEMIA			
subjects affected / exposed	2 / 4 (50.00%)	3 / 10 (30.00%)	12 / 20 (60.00%)
occurrences (all)	2	9	32
HYPERKALAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERMAGNESAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERPHOSPHATAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERTRIGLYCERIDAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1

HYPERURICAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOALBUMINAEMIA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	3
HYPOCALCAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	2 / 10 (20.00%)	5 / 20 (25.00%)
occurrences (all)	0	5	8
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	5 / 20 (25.00%)
occurrences (all)	0	0	8
HYPONATRAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
HYPOPHAGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	3 / 20 (15.00%)
occurrences (all)	0	1	3
HYPOVOLAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LACTIC ACIDOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MALNUTRITION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

POLYDIPSIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1

Non-serious adverse events	Phase I, Stage 2: Cohort A - GDC-0032 9 mg QD	Phase I,Stage 2:Cohort C- GDC-0032 9 mg QD+Midazolam 5 mg	Phase I,Stage 2: Cohort E-GDC-0032 6mg QD+Letrozole 2.5mg QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 20 (100.00%)	12 / 13 (92.31%)	20 / 20 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BENIGN NEOPLASM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
BRAIN NEOPLASM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HAEMANGIOMA OF SKIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
LIP NEOPLASM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
PAPILLOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TUMOUR FISTULISATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TUMOUR PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
DEEP VEIN THROMBOSIS			

subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
EMBOLISM VENOUS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FLUSHING			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
HAEMATOMA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
HOT FLUSH			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
HYPOTENSION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
JUGULAR VEIN THROMBOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
LYMPHOEDEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	2 / 20 (10.00%)	1 / 13 (7.69%)	5 / 20 (25.00%)
occurrences (all)	4	1	9
AXILLARY PAIN			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
CATHETER SITE ERYTHEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE INFLAMMATION			

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE OEDEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE RASH			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
CHEST DISCOMFORT			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CHEST PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CHILLS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	3 / 20 (15.00%)
occurrences (all)	0	1	3
DEVICE RELATED THROMBOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EARLY SATIETY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FATIGUE			
subjects affected / exposed	12 / 20 (60.00%)	10 / 13 (76.92%)	9 / 20 (45.00%)
occurrences (all)	18	13	15
GAIT DISTURBANCE			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GENERALISED OEDEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	2

INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE ERYTHEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE REACTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MALAISE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUCOSAL INFLAMMATION			
subjects affected / exposed	3 / 20 (15.00%)	2 / 13 (15.38%)	4 / 20 (20.00%)
occurrences (all)	6	4	15
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
OEDEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
OEDEMA PERIPHERAL			
subjects affected / exposed	2 / 20 (10.00%)	3 / 13 (23.08%)	3 / 20 (15.00%)
occurrences (all)	2	4	4
PAIN			
subjects affected / exposed	0 / 20 (0.00%)	2 / 13 (15.38%)	1 / 20 (5.00%)
occurrences (all)	0	2	1
PERIPHERAL SWELLING			

subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
PYREXIA			
subjects affected / exposed	3 / 20 (15.00%)	1 / 13 (7.69%)	5 / 20 (25.00%)
occurrences (all)	3	1	6
XEROSIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Immune system disorders			
CONTRAST MEDIA ALLERGY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERSENSITIVITY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SEASONAL ALLERGY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
BREAST DISCHARGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BREAST MASS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BREAST PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DYSPAREUNIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MENOPAUSAL SYMPTOMS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
PELVIC PAIN			

subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
PENILE HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
UTERINE PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VAGINAL DISCHARGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
VAGINAL HAEMORRHAGE			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
VULVAL DISORDER			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
VULVOVAGINAL BURNING SENSATION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
VULVOVAGINAL DRYNESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL INFLAMMATION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
VULVOVAGINAL PRURITUS			

subjects affected / exposed	2 / 20 (10.00%)	3 / 13 (23.08%)	3 / 20 (15.00%)
occurrences (all)	2	5	5
DYSPHONIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DYSPNOEA			
subjects affected / exposed	4 / 20 (20.00%)	3 / 13 (23.08%)	4 / 20 (20.00%)
occurrences (all)	5	5	6
DYSPNOEA EXERTIONAL			
subjects affected / exposed	1 / 20 (5.00%)	1 / 13 (7.69%)	2 / 20 (10.00%)
occurrences (all)	1	1	2
EPISTAXIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
HAEMOPTYSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HICCUPS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
HYPOXIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
INCREASED UPPER AIRWAY SECRETION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
INTERSTITIAL LUNG DISEASE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LARYNGEAL INFLAMMATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LOWER RESPIRATORY TRACT CONGESTION			

subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
LUNG CONSOLIDATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
NASAL CONGESTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NASAL DRYNESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL DISCOMFORT			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
PAINFUL RESPIRATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PARANASAL SINUS DISCOMFORT			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PARANASAL SINUS HYPERSECRETION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PLEURAL EFFUSION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	4
PLEURITIC PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA ASPIRATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1

PNEUMONITIS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
PULMONARY OEDEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
RHINITIS ALLERGIC			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RHINORRHOEA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
SINUS CONGESTION			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
SNEEZING			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
WHEEZING			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

ANXIETY			
subjects affected / exposed	2 / 20 (10.00%)	0 / 13 (0.00%)	3 / 20 (15.00%)
occurrences (all)	2	0	3
DEPRESSION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	3
AGITATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
INSOMNIA			
subjects affected / exposed	2 / 20 (10.00%)	1 / 13 (7.69%)	1 / 20 (5.00%)
occurrences (all)	2	1	1
LIBIDO DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
MIXED ANXIETY AND DEPRESSIVE DISORDER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MOOD ALTERED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MOOD SWINGS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Investigations			
WEIGHT DECREASED			
subjects affected / exposed	3 / 20 (15.00%)	0 / 13 (0.00%)	4 / 20 (20.00%)
occurrences (all)	3	0	7
ALANINE AMINOTRANSFERASE ABNORMAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ALANINE AMINOTRANSFERASE INCREASED			

subjects affected / exposed	3 / 20 (15.00%)	1 / 13 (7.69%)	2 / 20 (10.00%)
occurrences (all)	6	1	2
AMYLASE INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
ASPARTATE AMINOTRANSFERASE ABNORMAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	5 / 20 (25.00%)	2 / 13 (15.38%)	5 / 20 (25.00%)
occurrences (all)	7	2	7
BAND NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	4 / 20 (20.00%)
occurrences (all)	1	0	5
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD CALCIUM DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	2
BLOOD CHLORIDE DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	6
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATININE INCREASED			

subjects affected / exposed	2 / 20 (10.00%)	2 / 13 (15.38%)	0 / 20 (0.00%)
occurrences (all)	3	4	0
BLOOD INSULIN INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD MAGNESIUM DECREASED			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
BLOOD MAGNESIUM INCREASED			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
BLOOD PHOSPHORUS INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
BLOOD POTASSIUM DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD TRIGLYCERIDES INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD UREA INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
ELECTROCARDIOGRAM QT PROLONGED			
subjects affected / exposed	1 / 20 (5.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR INCREASED			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
INTERNATIONAL NORMALISED RATIO INCREASED			

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INVESTIGATION ABNORMAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LIPASE INCREASED			
subjects affected / exposed	2 / 20 (10.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	3	0	0
LIVER FUNCTION TEST INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
LOW DENSITY LIPOPROTEIN INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PLATELET COUNT DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
STREPTOCOCCUS TEST POSITIVE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	2
TROPONIN INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
WEIGHT INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1

WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
FALL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ANIMAL BITE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BURN ORAL CAVITY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CHEST INJURY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
CONTUSION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ESCHAR			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EYE INJURY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HIP FRACTURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LIMB FRACTURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LIMB INJURY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
POST PROCEDURAL HAEMORRHAGE			

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PROCEDURAL PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RADIATION SKIN INJURY			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
RIB FRACTURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
SKIN ABRASION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
SKIN LACERATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
SPINAL COMPRESSION FRACTURE			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
SUNBURN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ULNA FRACTURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
ANGINA PECTORIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ARRHYTHMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

ATRIOVENTRICULAR BLOCK FIRST DEGREE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BRADYCARDIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BUNDLE BRANCH BLOCK LEFT			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LEFT VENTRICULAR FAILURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
MITRAL VALVE INCOMPETENCE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
PALPITATIONS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
SINUS TACHYCARDIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
TACHYCARDIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	0 / 20 (0.00%)	4 / 13 (30.77%)	3 / 20 (15.00%)
occurrences (all)	0	4	5
HEADACHE			
subjects affected / exposed	3 / 20 (15.00%)	1 / 13 (7.69%)	2 / 20 (10.00%)
occurrences (all)	4	1	3
BALANCE DISORDER			

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CARPAL TUNNEL SYNDROME			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DISTURBANCE IN ATTENTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DYSAESTHESIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DYSARTHRIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DYSGEUSIA			
subjects affected / exposed	1 / 20 (5.00%)	2 / 13 (15.38%)	3 / 20 (15.00%)
occurrences (all)	1	3	3
HYPERSOMNIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOAESTHESIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LETHARGY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MEMORY IMPAIRMENT			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MIGRAINE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
MUSCLE SPASTICITY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NEURALGIA			

subjects affected / exposed	0 / 20 (0.00%)0 / 20 (0.00%)

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	1 / 20 (5.00%)	2 / 13 (15.38%)	5 / 20 (25.00%)
occurrences (all)	1	4	11
DISSEMINATED INTRAVASCULAR COAGULATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
IRON DEFICIENCY ANAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
LEUKOPENIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LYMPHOPENIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NEUTROPENIA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	3 / 20 (15.00%)
occurrences (all)	1	0	5
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
DEAFNESS UNILATERAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
EAR PAIN			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
EXCESSIVE CERUMEN PRODUCTION			

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOACUSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MOTION SICKNESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TINNITUS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VERTIGO			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
DIPLOPIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DRY EYE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
EXOPHTHALMOS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
EYE IRRITATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EYE PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
EYE SWELLING			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EYELID DISORDER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

EYELID PTOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
GLAUCOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LACRIMATION INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
OCULAR HYPERAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ORBITAL OEDEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
PERIORBITAL OEDEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PERIORBITAL SWELLING			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PHOTOPHOBIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PHOTOPSIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SCLERAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	2 / 20 (10.00%)
occurrences (all)	1	0	2
VISUAL IMPAIRMENT			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

VITREOUS FLOATERS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
DIARRHOEA			
subjects affected / exposed	10 / 20 (50.00%)	9 / 13 (69.23%)	15 / 20 (75.00%)
occurrences (all)	52	13	38
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
ABDOMINAL PAIN			
subjects affected / exposed	2 / 20 (10.00%)	3 / 13 (23.08%)	3 / 20 (15.00%)
occurrences (all)	2	4	3
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	1 / 20 (5.00%)	1 / 13 (7.69%)	1 / 20 (5.00%)
occurrences (all)	1	1	1
ABDOMINAL WALL HAEMATOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
ANAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
ANORECTAL DISCOMFORT			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
APHTHOUS ULCER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ASCITES			

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CHAPPED LIPS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CHEILITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
COLITIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
CONSTIPATION			
subjects affected / exposed	4 / 20 (20.00%)	1 / 13 (7.69%)	1 / 20 (5.00%)
occurrences (all)	5	1	1
DENTAL CARIES			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
DIVERTICULUM INTESTINAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DRY MOUTH			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	3 / 20 (15.00%)
occurrences (all)	1	0	3
DYSPEPSIA			
subjects affected / exposed	2 / 20 (10.00%)	3 / 13 (23.08%)	0 / 20 (0.00%)
occurrences (all)	3	3	0
DYSPHAGIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	2 / 20 (10.00%)
occurrences (all)	0	1	2
EPIGASTRIC DISCOMFORT			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
ERUCTATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FAECES DISCOLOURED			

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FLATULENCE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FREQUENT BOWEL MOVEMENTS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GASTRIC ULCER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GASTRITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	3 / 20 (15.00%)	0 / 13 (0.00%)	5 / 20 (25.00%)
occurrences (all)	4	0	5
GINGIVAL PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GLOSSITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GLOSSODYNIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HAEMATOCHEZIA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
HAEMORRHOIDS			
subjects affected / exposed	1 / 20 (5.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
HYPERCHLORHYDRIA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0

HYPOAESTHESIA ORAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LARGE INTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LIP PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MESENTERIC ARTERY THROMBOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MOUTH ULCERATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
NAUSEA			
subjects affected / exposed	9 / 20 (45.00%)	6 / 13 (46.15%)	13 / 20 (65.00%)
occurrences (all)	11	7	17
ODYNOPHAGIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
OESOPHAGEAL PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
OESOPHAGITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ORAL DYSAESTHESIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ORAL PAIN			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
PARAESTHESIA ORAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1

PERIODONTAL DISEASE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PROCTALGIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
PROCTITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
RECTAL TENESMUS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RETCHING			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	3 / 20 (15.00%)	0 / 13 (0.00%)	9 / 20 (45.00%)
occurrences (all)	5	0	11
TOOTHACHE			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
VARICOSE VEINS SUBLINGUAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VOMITING			
subjects affected / exposed	3 / 20 (15.00%)	5 / 13 (38.46%)	9 / 20 (45.00%)
occurrences (all)	5	5	12
Hepatobiliary disorders			
HEPATIC PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERBILIRUBINAEMIA			

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
RASH			
subjects affected / exposed	8 / 20 (40.00%)	2 / 13 (15.38%)	5 / 20 (25.00%)
occurrences (all)	15	2	13
ALOPECIA			
subjects affected / exposed	2 / 20 (10.00%)	0 / 13 (0.00%)	4 / 20 (20.00%)
occurrences (all)	2	0	4
BLISTER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
COLD SWEAT			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DECUBITUS ULCER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	2
DERMATITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DERMATITIS ALLERGIC			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DERMATITIS EXFOLIATIVE GENERALISED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DRY SKIN			
subjects affected / exposed	4 / 20 (20.00%)	0 / 13 (0.00%)	3 / 20 (15.00%)
occurrences (all)	4	0	3
DYSHIDROTIC ECZEMA			

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ECCHYMOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ECZEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ECZEMA ASTEATOTIC			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ERYTHEMA			
subjects affected / exposed	2 / 20 (10.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	2	0	1
EXFOLIATIVE RASH			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERHIDROSIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
INGROWING NAIL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
NAIL DISCOLOURATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NAIL DISORDER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NAIL DYSTROPHY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NIGHT SWEATS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
ONYCHOCLASIS			

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
ONYCHOLYSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
ONYCHOMADESIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PAIN OF SKIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
PAPU			

RASH MACULO-PAPULAR			
subjects affected / exposed	2 / 20 (10.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
RASH PAPULAR			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RASH VESICULAR			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ROSACEA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SEBORRHOEIC DERMATITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
SKIN EXFOLIATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
SKIN FISSURES			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
SKIN HYPERPIGMENTATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN PLAQUE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN TIGHTNESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN ULCER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URTICARIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
AZOTAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLADDER DISCOMFORT			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLADDER SPASM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CHROMATURIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CYSTITIS NONINFECTIVE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DYSURIA			
subjects affected / exposed	1 / 20 (5.00%)	2 / 13 (15.38%)	0 / 20 (0.00%)
occurrences (all)	1	2	0
HAEMATURIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
HYDRONEPHROSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MICTURITION URGENCY			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
POLLAKIURIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
POLYURIA			

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
PROTEINURIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RENAL FAILURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URETERIC OBSTRUCTION			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
URETERIC STENOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URINARY HESITATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
URINARY RETENTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	4 / 20 (20.00%)	0 / 13 (0.00%)	3 / 20 (15.00%)
occurrences (all)	6	0	3
ARTHRALGIA			
subjects affected / exposed	2 / 20 (10.00%)	0 / 13 (0.00%)	5 / 20 (25.00%)
occurrences (all)	5	0	8
ARTHRITIS			

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BONE PAIN			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
FLANK PAIN			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
GROIN PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INTERVERTEBRAL DISC PROTRUSION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
JOINT RANGE OF MOTION DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
JOINT SWELLING			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
MUSCLE DISORDER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	3 / 20 (15.00%)	0 / 13 (0.00%)	3 / 20 (15.00%)
occurrences (all)	3	0	4
MUSCLE TIGHTNESS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	1 / 20 (5.00%)
occurrences (all)	0	2	1
MUSCULOSKELETAL CHEST PAIN			

subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	2 / 20 (10.00%)
occurrences (all)	1	0	2
MUSCULOSKELETAL DISCOMFORT			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
MUSCULOSKELETAL STIFFNESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
MYALGIA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	3 / 20 (15.00%)
occurrences (all)	1	0	3
NECK PAIN			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	3
OSTEONECROSIS OF JAW			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
PAIN IN EXTREMITY			
subjects affected / exposed	2 / 20 (10.00%)	2 / 13 (15.38%)	1 / 20 (5.00%)
occurrences (all)	2	2	2
PAIN IN JAW			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SPINAL PAIN			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	2 / 20 (10.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
NASOPHARYNGITIS			
subjects affected / exposed	2 / 20 (10.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	2	0	1

UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	2 / 20 (10.00%)	1 / 13 (7.69%)	5 / 20 (25.00%)
occurrences (all)	2	1	7
URINARY TRACT INFECTION			
subjects affected / exposed	2 / 20 (10.00%)	0 / 13 (0.00%)	3 / 20 (15.00%)
occurrences (all)	2	0	3
BACTERAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CANDIDA INFECTION			
subjects affected / exposed	1 / 20 (5.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
CATHETER SITE INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CELLULITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
CONJUNCTIVITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	2
CONJUNCTIVITIS VIRAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CYSTITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CYTOMEGALOVIRUS INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DEVICE RELATED INFECTION			

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DIENTAMOEBA INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EAR INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ERYTHEMA INDURATUM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FUNGAL INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FUNGAL SKIN INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
FURUNCLE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GASTROINTESTINAL VIRAL INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GINGIVITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GROIN ABSCESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HERPES ZOSTER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HORDEOLUM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

LARYNGITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LOCALISED INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MASTITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUCOSAL INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NAIL INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
ORAL HERPES			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PARONYCHIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
PHARYNGITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
PURULENT DISCHARGE			

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PYELONEPHRITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY SYNCYTIAL VIRUS INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
SINUSITIS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
SKIN CANDIDA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
STOMA SITE INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TOOTH ABSCESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TOOTH INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT INFECTION BACTERIAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VAGINAL INFECTION			

subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VARICELLA ZOSTER VIRUS INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	2
VIRAL INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL MYCOTIC INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	8 / 20 (40.00%)	5 / 13 (38.46%)	7 / 20 (35.00%)
occurrences (all)	13	6	12
DEHYDRATION			
subjects affected / exposed	1 / 20 (5.00%)	3 / 13 (23.08%)	6 / 20 (30.00%)
occurrences (all)	2	5	18
ELECTROLYTE IMBALANCE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FAILURE TO THRIVE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FLUID OVERLOAD			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GLUCOSE TOLERANCE IMPAIRED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERCALCAEMIA			

subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
HYPERCHOLESTEROLAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERGLYCAEMIA			
subjects affected / exposed	5 / 20 (25.00%)	3 / 13 (23.08%)	9 / 20 (45.00%)
occurrences (all)	10	9	21
HYPERKALAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
HYPERMAGNESAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
HYPERPHOSPHATAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERTRIGLYCERIDAEMIA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 13 (0.00%)	2 / 20 (10.00%)
occurrences (all)	1	0	3
HYPERURICAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOCALCAEMIA			
subjects affected / exposed	1 / 20 (5.00%)	1 / 13 (7.69%)	1 / 20 (5.00%)
occurrences (all)	1	3	1
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			
subjects affected / exposed	5 / 20 (25.00%)	2 / 13 (15.38%)	7 / 20 (35.00%)
occurrences (all)	7	4	7
HYPOMAGNESAEMIA			

subjects affected / exposed	2 / 20 (10.00%)	0 / 13 (0.00%)	3 / 20 (15.00%)
occurrences (all)	2	0	4
HYPONATRAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
HYPOPHAGIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 13 (7.69%)	1 / 20 (5.00%)
occurrences (all)	0	3	1
HYPOVOLAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
LACTIC ACIDOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MALNUTRITION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
POLYDIPSIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 13 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase I, Stage 2: Cohort D - GDC-0032 9 mg QD	Phase I,Stage 2: Cohort E-GDC-0032 9mg QD+Letrozole 2.5mg QD	Phase I,Stage 2:Cohort F-GDC-0032 6mg QD+Fulvestrant 500mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 10 (100.00%)	7 / 8 (87.50%)	21 / 21 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BENIGN NEOPLASM			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
BRAIN NEOPLASM			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

HAEMANGIOMA OF SKIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LIP NEOPLASM			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PAPILLOMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
TUMOUR FISTULISATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
TUMOUR PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
EMBOLISM VENOUS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
FLUSHING			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
HAEMATOMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HOT FLUSH			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	2 / 21 (9.52%)
occurrences (all)	0	1	2
HYPOTENSION			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
JUGULAR VEIN THROMBOSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LYMPHOEDEMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	0 / 10 (0.00%)	3 / 8 (37.50%)	6 / 21 (28.57%)
occurrences (all)	0	4	11
AXILLARY PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE ERYTHEMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE INFLAMMATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE OEDEMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE RASH			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CHEST DISCOMFORT			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
CHEST PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
CHILLS			

subjects affected / exposed	2 / 10 (20.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	2	0	1
DEVICE RELATED THROMBOSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
EARLY SATIETY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
FATIGUE			
subjects affected / exposed	5 / 10 (50.00%)	2 / 8 (25.00%)	9 / 21 (42.86%)
occurrences (all)	5	2	20
GAIT DISTURBANCE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
GENERALISED OEDEMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE ERYTHEMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
INJECTION SITE PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE REACTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
MALAISE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	2

MUCOSAL INFLAMMATION			
subjects affected / exposed	1 / 10 (10.00%)	2 / 8 (25.00%)	3 / 21 (14.29%)
occurrences (all)	3	2	3
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
OEDEMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
OEDEMA PERIPHERAL			
subjects affected / exposed	1 / 10 (10.00%)	1 / 8 (12.50%)	1 / 21 (4.76%)
occurrences (all)	1	1	2
PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
PERIPHERAL SWELLING			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	2 / 21 (9.52%)
occurrences (all)	0	1	3
PYREXIA			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	4 / 21 (19.05%)
occurrences (all)	1	0	4
XEROSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
CONTRAST MEDIA ALLERGY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYPERSENSITIVITY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SEASONAL ALLERGY			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
BREAST DISCHARGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
BREAST MASS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
BREAST PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
DYSPAREUNIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MENOPAUSAL SYMPTOMS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PELVIC PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
PENILE HAEMORRHAGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
UTERINE PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
VAGINAL DISCHARGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
VAGINAL HAEMORRHAGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
VULVAL DISORDER			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL BURNING SENSATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL DRYNESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL INFLAMMATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL PRURITUS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
BRONCHOSPASM			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
COUGH			
subjects affected / exposed	1 / 10 (10.00%)	1 / 8 (12.50%)	6 / 21 (28.57%)
occurrences (all)	1	1	6
DYSPHONIA			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
DYSPNOEA			
subjects affected / exposed	3 / 10 (30.00%)	1 / 8 (12.50%)	4 / 21 (19.05%)
occurrences (all)	4	1	4
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
EPISTAXIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HAEMOPTYSIS			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HICCUPS			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
HYPOXIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
INCREASED UPPER AIRWAY SECRETION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
INTERSTITIAL LUNG DISEASE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LARYNGEAL INFLAMMATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LOWER RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LUNG CONSOLIDATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
NASAL CONGESTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
NASAL DRYNESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL DISCOMFORT			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
OROPHARYNGEAL PAIN			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PAINFUL RESPIRATION			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
PARANASAL SINUS DISCOMFORT			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PARANASAL SINUS HYPERSECRETION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PLEURAL EFFUSION			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	2 / 21 (9.52%)
occurrences (all)	1	0	2
PLEURITIC PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA ASPIRATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PNEUMONITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	2
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PULMONARY OEDEMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
RHINITIS ALLERGIC			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

RHINORRHOEA			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	0 / 21 (0.00%)
occurrences (all)	0	2	0
SINUS CONGESTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SNEEZING			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
WHEEZING			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	2 / 21 (9.52%)
occurrences (all)	2	0	2
DEPRESSION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
AGITATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
INSOMNIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	3 / 21 (14.29%)
occurrences (all)	0	0	3
LIBIDO DECREASED			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MIXED ANXIETY AND DEPRESSIVE DISORDER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MOOD ALTERED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MOOD SWINGS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Investigations			
WEIGHT DECREASED			
subjects affected / exposed	1 / 10 (10.00%)	2 / 8 (25.00%)	0 / 21 (0.00%)
occurrences (all)	2	2	0
ALANINE AMINOTRANSFERASE ABNORMAL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 10 (10.00%)	2 / 8 (25.00%)	7 / 21 (33.33%)
occurrences (all)	2	2	13
AMYLASE INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ASPARTATE AMINOTRANSFERASE ABNORMAL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	2 / 10 (20.00%)	2 / 8 (25.00%)	8 / 21 (38.10%)
occurrences (all)	4	5	13
BAND NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	3 / 8 (37.50%)	5 / 21 (23.81%)
occurrences (all)	0	5	6
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	1 / 21 (4.76%)
occurrences (all)	0	1	1

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
BLOOD TRIGLYCERIDES INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
BLOOD UREA INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
ELECTROCARDIOGRAM QT PROLONGED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	0 / 21 (0.00%)
occurrences (all)	0	2	0
HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
INVESTIGATION ABNORMAL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LIPASE INCREASED			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
LIVER FUNCTION TEST INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
LOW DENSITY LIPOPROTEIN INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LYMPHOCYTE COUNT DECREASED			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	2
PLATELET COUNT DECREASED			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	2
STREPTOCOCCUS TEST POSITIVE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
TROPONIN INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
WEIGHT INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
FALL			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
ANIMAL BITE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
BURN ORAL CAVITY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CHEST INJURY			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CONTUSION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
ESCHAR			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
EYE INJURY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HIP FRACTURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LIMB FRACTURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LIMB INJURY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
POST PROCEDURAL HAEMORRHAGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PROCEDURAL PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
RADIATION SKIN INJURY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
RIB FRACTURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SKIN ABRASION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SKIN LACERATION			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SPINAL COMPRESSION FRACTURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SUNBURN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ULNA FRACTURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
ANGINA PECTORIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ARRHYTHMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ATRIOVENTRICULAR BLOCK FIRST DEGREE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
BRADYCARDIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
BUNDLE BRANCH BLOCK LEFT			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LEFT VENTRICULAR FAILURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MITRAL VALVE INCOMPETENCE			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PALPITATIONS			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
SINUS TACHYCARDIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
TACHYCARDIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	3 / 10 (30.00%)	2 / 8 (25.00%)	6 / 21 (28.57%)
occurrences (all)	4	2	9
HEADACHE			
subjects affected / exposed	2 / 10 (20.00%)	1 / 8 (12.50%)	5 / 21 (23.81%)
occurrences (all)	2	3	14
BALANCE DISORDER			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
CARPAL TUNNEL SYNDROME			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
DISTURBANCE IN ATTENTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
DYSAESTHESIA			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
DYSARTHRIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

DYSGEUSIA			
subjects affected / exposed	1 / 10 (10.00%)	3 / 8 (37.50%)	2 / 21 (9.52%)
occurrences (all)	1	7	2
HYPERSOMNIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYPOAESTHESIA			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
LETHARGY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MEMORY IMPAIRMENT			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
MIGRAINE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
MUSCLE SPASTICITY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
NEURALGIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
PARAESTHESIA			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
PAROSMIA			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

PRESYNCOPE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SCIATICA			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
SEIZURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SINUS HEADACHE			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
SOMNOLENCE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SYNCOPE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
TASTE DISORDER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
TREMOR			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	6 / 21 (28.57%)
occurrences (all)	0	1	10
DISSEMINATED INTRAVASCULAR COAGULATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
IRON DEFICIENCY ANAEMIA			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LEUKOPENIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LYMPHOPENIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
NEUTROPENIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	3 / 21 (14.29%)
occurrences (all)	0	0	24
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
Ear and labyrinth disorders			
DEAFNESS UNILATERAL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
EAR PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
EXCESSIVE CERUMEN PRODUCTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYPOACUSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MOTION SICKNESS			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
TINNITUS			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
VERTIGO			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Eye disorders			
DIPLOPIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
DRY EYE			
subjects affected / exposed	2 / 10 (20.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
EXOPHTHALMOS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
EYE IRRITATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
EYE PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
EYE SWELLING			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
EYELID DISORDER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
EYELID PTOSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
GLAUCOMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LACRIMATION INCREASED			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
OCULAR HYPERAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ORBITAL OEDEMA			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PERIORBITAL OEDEMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PERIORBITAL SWELLING			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PHOTOPHOBIA			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
PHOTOPSIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
SCLERAL HAEMORRHAGE			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
VISION BLURRED			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	3 / 21 (14.29%)
occurrences (all)	1	0	3
VISUAL IMPAIRMENT			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
VITREOUS FLOATERS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
DIARRHOEA			
subjects affected / exposed	5 / 10 (50.00%)	6 / 8 (75.00%)	14 / 21 (66.67%)
occurrences (all)	10	11	42
ABDOMINAL DISCOMFORT			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	3 / 21 (14.29%)
occurrences (all)	1	0	5
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	2 / 21 (9.52%)
occurrences (all)	0	1	2

ABDOMINAL PAIN			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	4 / 21 (19.05%)
occurrences (all)	0	1	6
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	3
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	4 / 21 (19.05%)
occurrences (all)	0	0	7
ABDOMINAL WALL HAEMATOMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ANAL HAEMORRHAGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ANORECTAL DISCOMFORT			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
APHTHOUS ULCER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

DENTAL CARIES			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
DIVERTICULUM INTESTINAL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
DRY MOUTH			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	2 / 21 (9.52%)
occurrences (all)	0	1	3
DYSPEPSIA			
subjects affected / exposed	0 / 10 (0.00%)	2 / 8 (25.00%)	1 / 21 (4.76%)
occurrences (all)	0	2	1
DYSPHAGIA			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
EPIGASTRIC DISCOMFORT			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ERUCTATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
FAECES DISCOLOURED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
FLATULENCE			
subjects affected / exposed	1 / 10 (10.00%)	1 / 8 (12.50%)	0 / 21 (0.00%)
occurrences (all)	3	1	0
FREQUENT BOWEL MOVEMENTS			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
GASTRIC ULCER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
GASTRITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	2 / 21 (9.52%)
occurrences (all)	1	0	2
GINGIVAL PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
GLOSSITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
GLOSSODYNIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HAEMATOCHEZIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HAEMORRHOIDS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYPERCHLORHYDRIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYPOAESTHESIA ORAL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LARGE INTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LIP PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MESENTERIC ARTERY THROMBOSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MOUTH ULCERATION			

subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
NAUSEA			
subjects affected / exposed	6 / 10 (60.00%)	5 / 8 (62.50%)	13 / 21 (61.90%)
occurrences (all)	7	6	26
ODYNOPHAGIA			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
OESOPHAGEAL PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
OESOPHAGITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ORAL DYSAESTHESIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
ORAL PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
PARAESTHESIA ORAL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PERIODONTAL DISEASE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PROCTALGIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PROCTITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
RECTAL TENESMUS			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
RETCHING			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	1 / 10 (10.00%)	2 / 8 (25.00%)	5 / 21 (23.81%)
occurrences (all)	1	6	7
TOOTHACHE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
VARICOSE VEINS SUBLINGUAL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
VOMITING			
subjects affected / exposed	2 / 10 (20.00%)	2 / 8 (25.00%)	8 / 21 (38.10%)
occurrences (all)	4	2	10
Hepatobiliary disorders			
HEPATIC PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
RASH			
subjects affected / exposed	3 / 10 (30.00%)	3 / 8 (37.50%)	6 / 21 (28.57%)
occurrences (all)	5	5	19
ALOPECIA			
subjects affected / exposed	2 / 10 (20.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	2	0	1
BLISTER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
COLD SWEAT			

subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
DECUBITUS ULCER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
DERMATITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
DERMATITIS ALLERGIC			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
DERMATITIS EXFOLIATIVE GENERALISED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
DRY SKIN			
subjects affected / exposed	0 / 10 (0.00%)	3 / 8 (37.50%)	3 / 21 (14.29%)
occurrences (all)	0	3	7
DYSHIDROTIC ECZEMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ECCHYMOSIS			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
ECZEMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ECZEMA ASTEATOTIC			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ERYTHEMA			
subjects affected / exposed	1 / 10 (10.00%)	1 / 8 (12.50%)	2 / 21 (9.52%)
occurrences (all)	1	1	2

EXFOLIATIVE RASH			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
INGROWING NAIL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
NAIL DISCOLOURATION			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
NAIL DISORDER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
NAIL DYSTROPHY			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
NIGHT SWEATS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ONYCHOCLASIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ONYCHOLYSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ONYCHOMADESIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PAIN OF SKIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PAPULE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PHOTOSENSITIVITY REACTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PRURITUS			
subjects affected / exposed	0 / 10 (0.00%)	4 / 8 (50.00%)	3 / 21 (14.29%)
occurrences (all)	0	7	7
PRURITUS ALLERGIC			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PSORIASIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
RASH MACULAR			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
RASH MACULO-PAPULAR			
subjects affected / exposed	1 / 10 (10.00%)	1 / 8 (12.50%)	2 / 21 (9.52%)
occurrences (all)	1	1	3
RASH PAPULAR			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
RASH VESICULAR			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ROSACEA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SEBORRHOEIC DERMATITIS			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SKIN EXFOLIATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SKIN FISSURES			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SKIN HYPERPIGMENTATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SKIN PLAQUE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SKIN TIGHTNESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SKIN ULCER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
URTICARIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
AZOTAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
BLADDER DISCOMFORT			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
BLADDER SPASM			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

CHROMATURIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CYSTITIS NONINFECTIVE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
DYSURIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	3
HAEMATURIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
HYDRONEPHROSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	3
MICTURITION URGENCY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
POLLAKIURIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
POLYURIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PROTEINURIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
RENAL FAILURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
URETERIC OBSTRUCTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
URETERIC STENOSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

URINARY HESITATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
URINARY RETENTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	5 / 21 (23.81%)
occurrences (all)	0	2	7
ARTHRALGIA			
subjects affected / exposed	2 / 10 (20.00%)	0 / 8 (0.00%)	3 / 21 (14.29%)
occurrences (all)	3	0	7
ARTHRITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
BONE PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	6
FLANK PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
GROIN PAIN			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
INTERVERTEBRAL DISC PROTRUSION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
JOINT RANGE OF MOTION DECREASED			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
JOINT SWELLING			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MUSCLE DISORDER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	3 / 10 (30.00%)	3 / 8 (37.50%)	5 / 21 (23.81%)
occurrences (all)	4	6	10
MUSCLE TIGHTNESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MUSCULAR WEAKNESS			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	3 / 21 (14.29%)
occurrences (all)	1	0	4
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
MUSCULOSKELETAL DISCOMFORT			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	3
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	2 / 21 (9.52%)
occurrences (all)	0	1	2
MUSCULOSKELETAL STIFFNESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MYALGIA			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	2 / 21 (9.52%)
occurrences (all)	1	0	2
NECK PAIN			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PAIN IN EXTREMITY			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	2 / 21 (9.52%)
occurrences (all)	1	0	3
PAIN IN JAW			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
SPINAL PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
NASOPHARYNGITIS			
subjects affected / exposed	1 / 10 (10.00%)	1 / 8 (12.50%)	1 / 21 (4.76%)
occurrences (all)	1	1	1
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	2 / 10 (20.00%)	1 / 8 (12.50%)	3 / 21 (14.29%)
occurrences (all)	2	1	3
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	3 / 21 (14.29%)
occurrences (all)	0	1	6
BACTERAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CANDIDA INFECTION			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
CATHETER SITE INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CELLULITIS			

subjects affected / exposed	2 / 10 (20.00%)	0 / 8 (0.00%)	2 / 21 (9.52%)
occurrences (all)	3	0	3
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
CONJUNCTIVITIS			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
CONJUNCTIVITIS VIRAL			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	0 / 21 (0.00%)
occurrences (all)	0	3	0
CYSTITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CYTOMEGALOVIRUS INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
DIENTAMOEBA INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
EAR INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ERYTHEMA INDURATUM			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
FUNGAL INFECTION			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
FUNGAL SKIN INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
FURUNCLE			

subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
GASTROINTESTINAL VIRAL INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
GINGIVITIS			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
GROIN ABSCESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HERPES ZOSTER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	2
HORDEOLUM			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LARYNGITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LOCALISED INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
MASTITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MUCOSAL INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
NAIL INFECTION			

subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
ORAL HERPES			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PARONYCHIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
PNEUMONIA			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
PURULENT DISCHARGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PYELONEPHRITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY SYNCYTIAL VIRUS INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SINUSITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SKIN CANDIDA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

SKIN INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
STOMA SITE INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
TOOTH ABSCESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
TOOTH INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT INFECTION BACTERIAL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
VAGINAL INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
VARICELLA ZOSTER VIRUS INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
VIRAL INFECTION			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL MYCOTIC INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	2 / 10 (20.00%)	3 / 8 (37.50%)	10 / 21 (47.62%)
occurrences (all)	3	3	17

DEHYDRATION			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	4 / 21 (19.05%)
occurrences (all)	0	3	4
ELECTROLYTE IMBALANCE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
FAILURE TO THRIVE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
FLUID OVERLOAD			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
GLUCOSE TOLERANCE IMPAIRED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
HYPERCALCAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYPERCHOLESTEROLAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYPERGLYCAEMIA			
subjects affected / exposed	5 / 10 (50.00%)	4 / 8 (50.00%)	8 / 21 (38.10%)
occurrences (all)	17	9	21
HYPERKALAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYPERMAGNESAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYPERPHOSPHATAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYPERTRIGLYCERIDAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

HYPERURICAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	2
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
HYPOCALCAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			
subjects affected / exposed	2 / 10 (20.00%)	3 / 8 (37.50%)	5 / 21 (23.81%)
occurrences (all)	4	4	6
HYPOMAGNESAEMIA			
subjects affected / exposed	2 / 10 (20.00%)	0 / 8 (0.00%)	2 / 21 (9.52%)
occurrences (all)	4	0	2
HYPONATRAEMIA			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	4 / 21 (19.05%)
occurrences (all)	1	0	9
HYPOPHAGIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	2
HYPOVOLAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LACTIC ACIDOSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MALNUTRITION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

POLYDIPSIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 8 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase I, Stage 2: Cohort J-GDC-0032 4mg+Fulvestrant 500mg	Phase I,Stage 2:Cohort F-GDC-0032 9mg QD+Fulvestrant	Phase I, Stage 2: Cohort G - GDC-0032 9 mg QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 20 (95.00%)	6 / 6 (100.00%)	21 / 21 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BENIGN NEOPLASM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
BRAIN NEOPLASM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HAEMANGIOMA OF SKIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LIP NEOPLASM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PAPILLOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
TUMOUR FISTULISATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
TUMOUR PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
DEEP VEIN THROMBOSIS			

subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
EMBOLISM VENOUS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
FLUSHING			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HAEMATOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HOT FLUSH			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYPOTENSION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
JUGULAR VEIN THROMBOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LYMPHOEDEMA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	3	0	0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	4 / 20 (20.00%)	2 / 6 (33.33%)	5 / 21 (23.81%)
occurrences (all)	8	4	8
AXILLARY PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE ERYTHEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE INFLAMMATION			

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE OEDEMA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
CATHETER SITE RASH			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CHEST DISCOMFORT			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
CHEST PAIN			
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
CHILLS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
DEVICE RELATED THROMBOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
EARLY SATIETY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
FATIGUE			
subjects affected / exposed	8 / 20 (40.00%)	1 / 6 (16.67%)	6 / 21 (28.57%)
occurrences (all)	18	1	12
GAIT DISTURBANCE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
GENERALISED OEDEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE ERYTHEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE PAIN			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
INJECTION SITE REACTION			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
MALAISE			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
MUCOSAL INFLAMMATION			
subjects affected / exposed	6 / 20 (30.00%)	1 / 6 (16.67%)	4 / 21 (19.05%)
occurrences (all)	13	1	7
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
OEDEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
OEDEMA PERIPHERAL			
subjects affected / exposed	2 / 20 (10.00%)	3 / 6 (50.00%)	3 / 21 (14.29%)
occurrences (all)	2	5	4
PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
PERIPHERAL SWELLING			

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PENILE HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
UTERINE PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
VAGINAL DISCHARGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
VAGINAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
VULVAL DISORDER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL BURNING SENSATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL DRYNESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL INFLAMMATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL PRURITUS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
BRONCHOSPASM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
COUGH			

subjects affected / exposed	5 / 20 (25.00%)	4 / 6 (66.67%)	4 / 21 (19.05%)
occurrences (all)	5	5	4
DYSPHONIA			
subjects affected / exposed	1 / 20 (5.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	1	3	0
DYSPNOEA			
subjects affected / exposed	3 / 20 (15.00%)	1 / 6 (16.67%)	5 / 21 (23.81%)
occurrences (all)	5	1	9
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
EPISTAXIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HAEMOPTYSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HICCUPS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYPOXIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
INCREASED UPPER AIRWAY SECRETION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
INTERSTITIAL LUNG DISEASE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LARYNGEAL INFLAMMATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LOWER RESPIRATORY TRACT CONGESTION			

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LUNG CONSOLIDATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
NASAL CONGESTION			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
NASAL DRYNESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL DISCOMFORT			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	1 / 20 (5.00%)	1 / 6 (16.67%)	1 / 21 (4.76%)
occurrences (all)	1	1	1
PAINFUL RESPIRATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PARANASAL SINUS DISCOMFORT			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PARANASAL SINUS HYPERSECRETION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PLEURAL EFFUSION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PLEURITIC PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA ASPIRATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

PNEUMONITIS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	1 / 21 (4.76%)
occurrences (all)	0	4	2
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PULMONARY OEDEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
RHINITIS ALLERGIC			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
RHINORRHOEA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SINUS CONGESTION			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
SNEEZING			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	1 / 20 (5.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	1	1	0
WHEEZING			
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			

ANXIETY			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
DEPRESSION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
AGITATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
INSOMNIA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
LIBIDO DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MIXED ANXIETY AND DEPRESSIVE DISORDER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MOOD ALTERED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MOOD SWINGS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Investigations			
WEIGHT DECREASED			
subjects affected / exposed	3 / 20 (15.00%)	0 / 6 (0.00%)	2 / 21 (9.52%)
occurrences (all)	4	0	3
ALANINE AMINOTRANSFERASE ABNORMAL			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
ALANINE AMINOTRANSFERASE INCREASED			

subjects affected / exposed	3 / 20 (15.00%)	3 / 6 (50.00%)	4 / 21 (19.05%)
occurrences (all)	5	6	5
AMYLASE INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
ASPARTATE AMINOTRANSFERASE ABNORMAL			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	2 / 20 (10.00%)	3 / 6 (50.00%)	6 / 21 (28.57%)
occurrences (all)	5	7	6
BAND NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	3 / 20 (15.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	4	0	1
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
BLOOD CALCIUM DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
BLOOD CHLORIDE DECREASED			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	1 / 20 (5.00%)	1 / 6 (16.67%)	1 / 21 (4.76%)
occurrences (all)	1	2	1
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATININE INCREASED			

subjects affected / exposed	2 / 20 (10.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	6	0	1
BLOOD INSULIN INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
BLOOD MAGNESIUM DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
BLOOD MAGNESIUM INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
BLOOD PHOSPHORUS INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
BLOOD POTASSIUM DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
BLOOD TRIGLYCERIDES INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
BLOOD UREA INCREASED			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
ELECTROCARDIOGRAM QT PROLONGED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	3 / 20 (15.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	3	0	1
HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
INTERNATIONAL NORMALISED RATIO INCREASED			

subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
INVESTIGATION ABNORMAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LIPASE INCREASED			
subjects affected / exposed	1 / 20 (5.00%)	1 / 6 (16.67%)	2 / 21 (9.52%)
occurrences (all)	3	1	3
LIVER FUNCTION TEST INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LOW DENSITY LIPOPROTEIN INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	4 / 20 (20.00%)	0 / 6 (0.00%)	2 / 21 (9.52%)
occurrences (all)	11	0	3
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	2 / 20 (10.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	5	0	0
PLATELET COUNT DECREASED			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	2 / 21 (9.52%)
occurrences (all)	1	0	2
STREPTOCOCCUS TEST POSITIVE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
TROPONIN INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
WEIGHT INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
FALL			
subjects affected / exposed	3 / 20 (15.00%)	2 / 6 (33.33%)	0 / 21 (0.00%)
occurrences (all)	5	3	0
ANIMAL BITE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
BURN ORAL CAVITY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CHEST INJURY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CONTUSION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ESCHAR			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
EYE INJURY			
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
HIP FRACTURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LIMB FRACTURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LIMB INJURY			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
POST PROCEDURAL HAEMORRHAGE			

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PROCEDURAL PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
RADIATION SKIN INJURY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
RIB FRACTURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SKIN ABRASION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SKIN LACERATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SPINAL COMPRESSION FRACTURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SUNBURN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ULNA FRACTURE			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
ANGINA PECTORIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
ARRHYTHMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

ATRIOVENTRICULAR BLOCK FIRST DEGREE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
BRADYCARDIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
BUNDLE BRANCH BLOCK LEFT			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
LEFT VENTRICULAR FAILURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MITRAL VALVE INCOMPETENCE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PALPITATIONS			
subjects affected / exposed	2 / 20 (10.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CARPAL TUNNEL SYNDROME			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
DISTURBANCE IN ATTENTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
DYSAESTHESIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
DYSARTHRIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
DYSGEUSIA			
subjects affected / exposed	2 / 20 (10.00%)	2 / 6 (33.33%)	1 / 21 (4.76%)
occurrences (all)	2	3	1
HYPERSOMNIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYPOAESTHESIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LETHARGY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MEMORY IMPAIRMENT			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
MIGRAINE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASTICITY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
NEURALGIA			

subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
PARAESTHESIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PAROSMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PRESYNCOPE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SCIATICA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SEIZURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SINUS HEADACHE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SOMNOLENCE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SYNCOPE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
TASTE DISORDER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
TREMOR			

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	3 / 20 (15.00%)	0 / 6 (0.00%)	4 / 21 (19.05%)
occurrences (all)	4	0	9
DISSEMINATED INTRAVASCULAR COAGULATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
IRON DEFICIENCY ANAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LEUKOPENIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LYMPHOPENIA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
NEUTROPENIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
DEAFNESS UNILATERAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
EAR PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
EXCESSIVE CERUMEN PRODUCTION			

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYPOACUSIS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
MOTION SICKNESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
TINNITUS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
VERTIGO			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
DIPLOPIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
DRY EYE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
EXOPHTHALMOS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
EYE IRRITATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
EYE PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
EYE SWELLING			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
EYELID DISORDER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

EYELID PTOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
GLAUCOMA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
LACRIMATION INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
OCULAR HYPERAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
ORBITAL OEDEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PERIORBITAL OEDEMA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
PERIORBITAL SWELLING			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PHOTOPHOBIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PHOTOPSIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SCLERAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
subjects affected / exposed	2 / 20 (10.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	6	1	0
VISUAL IMPAIRMENT			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

VITREOUS FLOATERS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
DIARRHOEA			
subjects affected / exposed	11 / 20 (55.00%)	4 / 6 (66.67%)	14 / 21 (66.67%)
occurrences (all)	85	25	44
ABDOMINAL DISCOMFORT			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN			
subjects affected / exposed	3 / 20 (15.00%)	2 / 6 (33.33%)	6 / 21 (28.57%)
occurrences (all)	5	2	9
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	1 / 20 (5.00%)	2 / 6 (33.33%)	2 / 21 (9.52%)
occurrences (all)	1	4	2
ABDOMINAL WALL HAEMATOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ANAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ANORECTAL DISCOMFORT			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
APHTHOUS ULCER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
ASCITES			

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CHAPPED LIPS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CHEILITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
COLITIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
CONSTIPATION			
subjects affected / exposed	2 / 20 (10.00%)	1 / 6 (16.67%)	3 / 21 (14.29%)
occurrences (all)	3	1	6
DENTAL CARIES			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
DIVERTICULUM INTESTINAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
DRY MOUTH			
subjects affected / exposed	1 / 20 (5.00%)	1 / 6 (16.67%)	2 / 21 (9.52%)
occurrences (all)	1	1	2
DYSPEPSIA			
subjects affected / exposed	5 / 20 (25.00%)	1 / 6 (16.67%)	2 / 21 (9.52%)
occurrences (all)	7	1	2
DYSPHAGIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
EPIGASTRIC DISCOMFORT			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ERUCTATION			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
FAECES DISCOLOURED			

subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
FLATULENCE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
FREQUENT BOWEL MOVEMENTS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
GASTRIC ULCER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
GASTRITIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
GINGIVAL PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
GLOSSITIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
GLOSSODYNIA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
HAEMATOCHEZIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
HAEMORRHOIDS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
HYPERCHLORHYDRIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

HYPOAESTHESIA ORAL			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
LARGE INTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
LIP PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MESENTERIC ARTERY THROMBOSIS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
MOUTH ULCERATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
NAUSEA			
subjects affected / exposed	7 / 20 (35.00%)	6 / 6 (100.00%)	14 / 21 (66.67%)
occurrences (all)	16	7	19
ODYNOPHAGIA			
subjects affected / exposed	0 / 20 (0.00%)	2 / 6 (33.33%)	0 / 21 (0.00%)
occurrences (all)	0	3	0
OESOPHAGEAL PAIN			
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
OESOPHAGITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ORAL DYSAESTHESIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ORAL PAIN			
subjects affected / exposed	1 / 20 (5.00%)	1 / 6 (16.67%)	1 / 21 (4.76%)
occurrences (all)	2	1	1
PARAESTHESIA ORAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

PERIODONTAL DISEASE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PROCTALGIA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
PROCTITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
RECTAL TENESMUS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
RETCHING			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	4 / 20 (20.00%)	3 / 6 (50.00%)	4 / 21 (19.05%)
occurrences (all)	5	4	4
TOOTHACHE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
VARICOSE VEINS SUBLINGUAL			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
VOMITING			
subjects affected / exposed	5 / 20 (25.00%)	4 / 6 (66.67%)	5 / 21 (23.81%)
occurrences (all)	10	6	11
Hepatobiliary disorders			
HEPATIC PAIN			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
HYPERBILIRUBINAEMIA			

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
RASH			
subjects affected / exposed	5 / 20 (25.00%)	4 / 6 (66.67%)	3 / 21 (14.29%)
occurrences (all)	7	6	6
ALOPECIA			
subjects affected / exposed	2 / 20 (10.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	2	1	0
BLISTER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
COLD SWEAT			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
DECUBITUS ULCER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
DERMATITIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
DERMATITIS ALLERGIC			
subjects affected / exposed		0 / 6 (0.00%)	0 / 21 (0.00%)

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ECCHYMOSIS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	1 / 21 (4.76%)
occurrences (all)	0	3	1
ECZEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ECZEMA ASTEATOTIC			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ERYTHEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
EXFOLIATIVE RASH			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
INGROWING NAIL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
NAIL DISCOLOURATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
NAIL DISORDER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
NAIL DYSTROPHY			
subjects affected / exposed	2 / 20 (10.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
NIGHT SWEATS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ONYCHOCLASIS			

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ONYCHOLYSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ONYCHOMADESIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PAIN OF SKIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
PAPULE			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
PHOTOSENSITIVITY REACTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PRURITUS			
subjects affected / exposed	1 / 20 (5.00%)	2 / 6 (33.33%)	4 / 21 (19.05%)
occurrences (all)	1	2	5
PRURITUS ALLERGIC			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PSORIASIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
RASH MACULAR			
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	0	1	0

RASH MACULO-PAPULAR			
subjects affected / exposed	2 / 20 (10.00%)	1 / 6 (16.67%)	2 / 21 (9.52%)
occurrences (all)	2	4	2
RASH PAPULAR			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
RASH VESICULAR			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ROSACEA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SEBORRHOEIC DERMATITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SKIN EXFOLIATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SKIN FISSURES			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SKIN HYPERPIGMENTATION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
SKIN PLAQUE			
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
SKIN TIGHTNESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SKIN ULCER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
URTICARIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2

Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
AZOTAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
BLADDER DISCOMFORT			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
BLADDER SPASM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CHROMATURIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CYSTITIS NONINFECTIVE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
DYSURIA			
subjects affected / exposed	2 / 20 (10.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	2	0	1
HAEMATURIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYDRONEPHROSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MICTURITION URGENCY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
POLLAKIURIA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
POLYURIA			

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PROTEINURIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
RENAL FAILURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
URETERIC OBSTRUCTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
URETERIC STENOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
URINARY HESITATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
URINARY RETENTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	3 / 20 (15.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	5	0	1
ARTHRALGIA			
subjects affected / exposed	3 / 20 (15.00%)	2 / 6 (33.33%)	1 / 21 (4.76%)
occurrences (all)	4	2	1
ARTHRITIS			

subjects affected / exposed	1 / 20 (5.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	2	1	0
BONE PAIN			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
FLANK PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
GROIN PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
INTERVERTEBRAL DISC PROTRUSION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
JOINT RANGE OF MOTION DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
JOINT SWELLING			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
MUSCLE DISORDER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	1 / 20 (5.00%)	3 / 6 (50.00%)	3 / 21 (14.29%)
occurrences (all)	1	5	4
MUSCLE TIGHTNESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MUSCULAR WEAKNESS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	2 / 21 (9.52%)
occurrences (all)	1	0	2
MUSCULOSKELETAL CHEST PAIN			

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL DISCOMFORT			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 20 (0.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
MUSCULOSKELETAL STIFFNESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MYALGIA			
subjects affected / exposed	2 / 20 (10.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
NECK PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
OSTEONECROSIS OF JAW			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PAIN IN EXTREMITY			
subjects affected / exposed	3 / 20 (15.00%)	1 / 6 (16.67%)	1 / 21 (4.76%)
occurrences (all)	4	1	1
PAIN IN JAW			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
SPINAL PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
NASOPHARYNGITIS			
subjects affected / exposed	3 / 20 (15.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	6	0	0

UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	4 / 20 (20.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	6	2	0
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
BACTERAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CANDIDA INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CELLULITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVITIS			
subjects affected / exposed	2 / 20 (10.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
CONJUNCTIVITIS VIRAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CYSTITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
CYTOMEGALOVIRUS INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
DEVICE RELATED INFECTION			

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
DIENTAMOEBA INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
EAR INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ERYTHEMA INDURATUM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
FUNGAL INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
FUNGAL SKIN INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
FURUNCLE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
GASTROINTESTINAL VIRAL INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
GINGIVITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
GROIN ABSCESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HERPES ZOSTER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HORDEOLUM			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0

LARYNGITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LOCALISED INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MASTITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MUCOSAL INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
NAIL INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
ORAL HERPES			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
PARONYCHIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
PNEUMONIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
PURULENT DISCHARGE			

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
PYELONEPHRITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY SYNCYTIAL VIRUS INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
SINUSITIS			
subjects affected / exposed	2 / 20 (10.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
SKIN CANDIDA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SKIN INFECTION			
subjects affected / exposed	2 / 20 (10.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
STOMA SITE INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
TOOTH ABSCESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
TOOTH INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
URINARY TRACT INFECTION BACTERIAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
VAGINAL INFECTION			

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
VARICELLA ZOSTER VIRUS INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)		0	0

subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYPERCHOLESTEROLAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYPERGLYCAEMIA			
subjects affected / exposed	6 / 20 (30.00%)	3 / 6 (50.00%)	8 / 21 (38.10%)
occurrences (all)	14	21	16
HYPERKALAEMIA			
subjects affected / exposed	2 / 20 (10.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
HYPERMAGNESAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYPERPHOSPHATAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYPERTRIGLYCERIDAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
HYPERURICAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	3
HYPOCALCAEMIA			
subjects affected / exposed	2 / 20 (10.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			
subjects affected / exposed	3 / 20 (15.00%)	4 / 6 (66.67%)	5 / 21 (23.81%)
occurrences (all)	4	13	8
HYPOMAGNESAEMIA			

subjects affected / exposed	3 / 20 (15.00%)	1 / 6 (16.67%)	4 / 21 (19.05%)
occurrences (all)	5	3	5
HYPONATRAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	4 / 21 (19.05%)
occurrences (all)	0	0	7
HYPOPHAGIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 6 (0.00%)	3 / 21 (14.29%)
occurrences (all)	1	0	3
HYPOVOLAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
LACTIC ACIDOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
MALNUTRITION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
POLYDIPSIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase I, Stage 2: Cohort H - GDC-0032 6 mg QD	Phase I,Stage 2: Cohort L-GDC-0032 4mg + Fulvestrant 500mg	Phase I,Stage 2: Cohort M-GDC-0032 2mg QD+Fulvestrant 500mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	35 / 35 (100.00%)	19 / 19 (100.00%)	20 / 20 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BENIGN NEOPLASM			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BRAIN NEOPLASM			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

HAEMANGIOMA OF SKIN			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LIP NEOPLASM			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PAPILLOMA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TUMOUR FISTULISATION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TUMOUR PAIN			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	1 / 35 (2.86%)	3 / 19 (15.79%)	1 / 20 (5.00%)
occurrences (all)	2	4	1
DEEP VEIN THROMBOSIS			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
EMBOLISM VENOUS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FLUSHING			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HAEMATOMA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HOT FLUSH			
subjects affected / exposed	0 / 35 (0.00%)	3 / 19 (15.79%)	0 / 20 (0.00%)
occurrences (all)	0	3	0
HYPOTENSION			

subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
JUGULAR VEIN THROMBOSIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LYMPHOEDEMA			
subjects affected / exposed	1 / 35 (2.86%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	2 / 35 (5.71%)	1 / 19 (5.26%)	4 / 20 (20.00%)
occurrences (all)	2	1	5
AXILLARY PAIN			
subjects affected / exposed	0 / 35 (0.00%)	2 / 19 (10.53%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
CATHETER SITE ERYTHEMA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE INFLAMMATION			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
CATHETER SITE OEDEMA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE RASH			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CHEST DISCOMFORT			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	2 / 20 (10.00%)
occurrences (all)	0	1	2
CHEST PAIN			
subjects affected / exposed	2 / 35 (5.71%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
CHILLS			

subjects affected / exposed	1 / 35 (2.86%)	1 / 19 (5.26%)	1 / 20 (5.00%)
occurrences (all)	1	1	1
DEVICE RELATED THROMBOSIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EARLY SATIETY			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FATIGUE			
subjects affected / exposed	9 / 35 (25.71%)	7 / 19 (36.84%)	6 / 20 (30.00%)
occurrences (all)	12	12	11
GAIT DISTURBANCE			
subjects affected / exposed	2 / 35 (5.71%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GENERALISED OEDEMA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
INJECTION SITE ERYTHEMA			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
INJECTION SITE PAIN			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE REACTION			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	3 / 20 (15.00%)
occurrences (all)	0	1	3
MALAISE			
subjects affected / exposed	1 / 35 (2.86%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	2	1	0

MUCOSAL INFLAMMATION			
subjects affected / exposed	4 / 35 (11.43%)	1 / 19 (5.26%)	1 / 20 (5.00%)
occurrences (all)	6	1	2
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
OEDEMA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
OEDEMA PERIPHERAL			
subjects affected / exposed	4 / 35 (11.43%)	2 / 19 (10.53%)	0 / 20 (0.00%)
occurrences (all)	7	2	0
PAIN			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
PERIPHERAL SWELLING			
subjects affected / exposed	2 / 35 (5.71%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
PYREXIA			
subjects affected / exposed	2 / 35 (5.71%)	2 / 19 (10.53%)	4 / 20 (20.00%)
occurrences (all)	3	4	5
XEROSIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
CONTRAST MEDIA ALLERGY			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
HYPERSENSITIVITY			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SEASONAL ALLERGY			

subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
BREAST DISCHARGE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BREAST MASS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
BREAST PAIN			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
DYSPAREUNIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MENOPAUSAL SYMPTOMS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PELVIC PAIN			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
PENILE HAEMORRHAGE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
UTERINE PAIN			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VAGINAL DISCHARGE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VAGINAL HAEMORRHAGE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VULVAL DISORDER			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL BURNING SENSATION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL DRYNESS			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
VULVOVAGINAL INFLAMMATION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL PRURITUS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
BRONCHOSPASM			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
COUGH			
subjects affected / exposed	3 / 35 (8.57%)	2 / 19 (10.53%)	3 / 20 (15.00%)
occurrences (all)	3	2	4
DYSPHONIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	2
DYSPNOEA			
subjects affected / exposed	6 / 35 (17.14%)	0 / 19 (0.00%)	4 / 20 (20.00%)
occurrences (all)	7	0	4
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
EPISTAXIS			
subjects affected / exposed	1 / 35 (2.86%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
HAEMOPTYSIS			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HICCUPS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOXIA			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
INCREASED UPPER AIRWAY SECRETION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INTERSTITIAL LUNG DISEASE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LARYNGEAL INFLAMMATION			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
LOWER RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LUNG CONSOLIDATION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NASAL CONGESTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	3 / 20 (15.00%)
occurrences (all)	0	0	3
NASAL DRYNESS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL DISCOMFORT			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL PAIN			

subjects affected / exposed	1 / 35 (2.86%)	3 / 19 (15.79%)	5 / 20 (25.00%)
occurrences (all)	1	3	6
PAINFUL RESPIRATION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PARANASAL SINUS DISCOMFORT			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PARANASAL SINUS HYPERSECRETION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PLEURAL EFFUSION			
subjects affected / exposed	2 / 35 (5.71%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	4	0	0
PLEURITIC PAIN			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
PNEUMONIA ASPIRATION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PNEUMONITIS			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
PRODUCTIVE COUGH			
subjects affected / exposed	2 / 35 (5.71%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	4	0	0
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PULMONARY OEDEMA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RHINITIS ALLERGIC			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

RHINORRHOEA			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
SINUS CONGESTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SNEEZING			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
		1	0

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
MIXED ANXIETY AND DEPRESSIVE DISORDER			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MOOD ALTERED			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MOOD SWINGS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Investigations			
WEIGHT DECREASED			
subjects affected / exposed	4 / 35 (11.43%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	4	1	0
ALANINE AMINOTRANSFERASE ABNORMAL			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 35 (2.86%)	2 / 19 (10.53%)	2 / 20 (10.00%)
occurrences (all)	1	11	5
AMYLASE INCREASED			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ASPARTATE AMINOTRANSFERASE ABNORMAL			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 35 (2.86%)	1 / 19 (5.26%)	4 / 20 (20.00%)
occurrences (all)	1	6	7
BAND NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	2 / 35 (5.71%)	0 / 19 (0.00%)	2 / 20 (10.00%)
occurrences (all)	2	0	2
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
BLOOD CALCIUM DECREASED			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD CHLORIDE DECREASED			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	2 / 35 (5.71%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	4	0	4
BLOOD INSULIN INCREASED			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD MAGNESIUM DECREASED			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD MAGNESIUM INCREASED			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD PHOSPHORUS INCREASED			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD POTASSIUM DECREASED			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD TRIGLYCERIDES INCREASED			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD UREA INCREASED			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ELECTROCARDIOGRAM QT PROLONGED			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR INCREASED			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INVESTIGATION ABNORMAL			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LIPASE INCREASED			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	1 / 20 (5.00%)
occurrences (all)	0	4	1
LIVER FUNCTION TEST INCREASED			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LOW DENSITY LIPOPROTEIN INCREASED			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
LYMPHOCYTE COUNT DECREASED			

subjects affected / exposed	3 / 35 (8.57%)	1 / 19 (5.26%)	1 / 20 (5.00%)
occurrences (all)	11	6	3
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	1 / 35 (2.86%)	1 / 19 (5.26%)	1 / 20 (5.00%)
occurrences (all)	1	1	1
PLATELET COUNT DECREASED			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
STREPTOCOCCUS TEST POSITIVE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TROPONIN INCREASED			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
WEIGHT INCREASED			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
FALL			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ANIMAL BITE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BURN ORAL CAVITY			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CHEST INJURY			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CONTUSION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
ESCHAR			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EYE INJURY			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HIP FRACTURE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LIMB FRACTURE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LIMB INJURY			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
POST PROCEDURAL HAEMORRHAGE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PROCEDURAL PAIN			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RADIATION SKIN INJURY			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RIB FRACTURE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN ABRASION			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
SKIN LACERATION			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SPINAL COMPRESSION FRACTURE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SUNBURN			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ULNA FRACTURE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
ANGINA PECTORIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ARRHYTHMIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ATRIOVENTRICULAR BLOCK FIRST DEGREE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BRADYCARDIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BUNDLE BRANCH BLOCK LEFT			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LEFT VENTRICULAR FAILURE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MITRAL VALVE INCOMPETENCE			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PALPITATIONS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
SINUS TACHYCARDIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TACHYCARDIA			
subjects affected / exposed	2 / 35 (5.71%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	3 / 35 (8.57%)	3 / 19 (15.79%)	3 / 20 (15.00%)
occurrences (all)	3	5	4
HEADACHE			
subjects affected / exposed	0 / 35 (0.00%)	6 / 19 (31.58%)	2 / 20 (10.00%)
occurrences (all)	0	6	3
BALANCE DISORDER			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CARPAL TUNNEL SYNDROME			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DISTURBANCE IN ATTENTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DYSAESTHESIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DYSARTHRIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

DYSGEUSIA			
subjects affected / exposed	3 / 35 (8.57%)	1 / 19 (5.26%)	2 / 20 (10.00%)
occurrences (all)	3	1	2
HYPERSOMNIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOAESTHESIA			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
LETHARGY			
subjects affected / exposed	2 / 35 (5.71%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	3	0	0
MEMORY IMPAIRMENT			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
MIGRAINE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
MUSCLE SPASTICITY			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NEURALGIA			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	2
PARAESTHESIA			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
PAROSMIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	1 / 35 (2.86%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	1	1	0

PRESYNCOPE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SCIATICA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SEIZURE			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
SINUS HEADACHE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SOMNOLENCE			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
SYNCOPE			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
TASTE DISORDER			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
TREMOR			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	5 / 35 (14.29%)	0 / 19 (0.00%)	2 / 20 (10.00%)
occurrences (all)	9	0	5
DISSEMINATED INTRAVASCULAR COAGULATION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
IRON DEFICIENCY ANAEMIA			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LEUKOPENIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LYMPHOPENIA			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	3	0	0
NEUTROPENIA			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	2
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
DEAFNESS UNILATERAL			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EAR PAIN			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EXCESSIVE CERUMEN PRODUCTION			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
HYPOACUSIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MOTION SICKNESS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TINNITUS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VERTIGO			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Eye disorders			
DIPLOPIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DRY EYE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
EXOPHTHALMOS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EYE IRRITATION			
subjects affected / exposed			0 / 20 (0.00%)

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PERIORBITAL OEDEMA			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
PERIORBITAL SWELLING			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PHOTOPHOBIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PHOTOPSIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SCLERAL HAEMORRHAGE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
VISUAL IMPAIRMENT			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VITREOUS FLOATERS			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
DIARRHOEA			
subjects affected / exposed	16 / 35 (45.71%)	11 / 19 (57.89%)	11 / 20 (55.00%)
occurrences (all)	30	27	27
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	3

ABDOMINAL PAIN			
subjects affected / exposed	6 / 35 (17.14%)	3 / 19 (15.79%)	1 / 20 (5.00%)
occurrences (all)	8	4	1
ABDOMINAL PAIN LOWER			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	2 / 35 (5.71%)	3 / 19 (15.79%)	1 / 20 (5.00%)
occurrences (all)	2	3	1
ABDOMINAL WALL HAEMATOMA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ANAL HAEMORRHAGE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ANORECTAL DISCOMFORT			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
APHTHOUS ULCER			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ASCITES			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
CHAPPED LIPS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CHEILITIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	2
COLITIS			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	2 / 20 (10.00%)
occurrences (all)	0	1	2
CONSTIPATION			
subjects affected / exposed	4 / 35 (11.43%)	6 / 19 (31.58%)	4 / 20 (20.00%)
occurrences (all)	4	7	4

DENTAL CARIES			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DIVERTICULUM INTESTINAL			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
DRY MOUTH			
subjects affected / exposed	0 / 35 (0.00%)	2 / 19 (10.53%)	1 / 20 (5.00%)
occurrences (all)	0	2	1
DYSPEPSIA			
subjects affected / exposed	1 / 35 (2.86%)	2 / 19 (10.53%)	2 / 20 (10.00%)
occurrences (all)	1	2	3
DYSPHAGIA			
subjects affected / exposed	2 / 35 (5.71%)	0 / 19 (0.00%)	3 / 20 (15.00%)
occurrences (all)	2	0	3
EPIGASTRIC DISCOMFORT			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ERUCTATION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FAECES DISCOLOURED			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FLATULENCE			
subjects affected / exposed	1 / 35 (2.86%)	2 / 19 (10.53%)	2 / 20 (10.00%)
occurrences (all)	1	2	2
FREQUENT BOWEL MOVEMENTS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GASTRIC ULCER			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GASTRITIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	2 / 20 (10.00%)
occurrences (all)	1	0	2
GINGIVAL PAIN			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
GLOSSITIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GLOSSODYNIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HAEMATOCHEZIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HAEMORRHOIDS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
HYPERCHLORHYDRIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOAESTHESIA ORAL			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LARGE INTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LIP PAIN			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MESENTERIC ARTERY THROMBOSIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MOUTH ULCERATION			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
NAUSEA			
subjects affected / exposed	11 / 35 (31.43%)	9 / 19 (47.37%)	9 / 20 (45.00%)
occurrences (all)	12	10	14
ODYNOPHAGIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
OESOPHAGEAL PAIN			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
OESOPHAGITIS			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
ORAL DYSAESTHESIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ORAL PAIN			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
PARAESTHESIA ORAL			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PERIODONTAL DISEASE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PROCTALGIA			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
PROCTITIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RECTAL TENESMUS			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RETCHING			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	7 / 35 (20.00%)	3 / 19 (15.79%)	3 / 20 (15.00%)
occurrences (all)	9	4	3
TOOTHACHE			
subjects affected / exposed	1 / 35 (2.86%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
VARICOSE VEINS SUBLINGUAL			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VOMITING			
subjects affected / exposed	4 / 35 (11.43%)	3 / 19 (15.79%)	2 / 20 (10.00%)
occurrences (all)	6	4	2
Hepatobiliary disorders			
HEPATIC PAIN			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
RASH			
subjects affected / exposed	4 / 35 (11.43%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	4	0	1
ALOPECIA			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
BLISTER			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
COLD SWEAT			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DECUBITUS ULCER			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
DERMATITIS			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
DERMATITIS ACNEIFORM			
subjects affected / exposed	2 / 35 (5.71%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	3	0	1
DERMATITIS ALLERGIC			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DERMATITIS EXFOLIATIVE GENERALISED			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DRY SKIN			
subjects affected / exposed	2 / 35 (5.71%)	2 / 19 (10.53%)	2 / 20 (10.00%)
occurrences (all)	2	2	2
DYSHIDROTIC ECZEMA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ECCHYMOSIS			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
ECZEMA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ECZEMA ASTEATOTIC			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ERYTHEMA			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0

EXFOLIATIVE RASH			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INGROWING NAIL			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NAIL DISCOLOURATION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NAIL DISORDER			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NAIL DYSTROPHY			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NIGHT SWEATS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ONYCHOCLASIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ONYCHOLYSIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ONYCHOMADESIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PAIN OF SKIN			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME			

subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
PAPULE			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
PHOTOSENSITIVITY REACTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PRURITUS			
subjects affected / exposed	3 / 35 (8.57%)	3 / 19 (15.79%)	2 / 20 (10.00%)
occurrences (all)	3	4	2
PRURITUS ALLERGIC			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PSORIASIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
RASH MACULAR			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RASH MACULO-PAPULAR			
subjects affected / exposed	3 / 35 (8.57%)	4 / 19 (21.05%)	3 / 20 (15.00%)
occurrences (all)	3	4	10
RASH PAPULAR			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RASH VESICULAR			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ROSACEA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SEBORRHOEIC DERMATITIS			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN EXFOLIATION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN FISSURES			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
SKIN HYPERPIGMENTATION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN PLAQUE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN TIGHTNESS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN ULCER			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
URTICARIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	1 / 35 (2.86%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
AZOTAEMIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLADDER DISCOMFORT			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLADDER SPASM			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

URINARY HESITATION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URINARY RETENTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
URINARY TRACT PAIN			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	5 / 35 (14.29%)	4 / 19 (21.05%)	4 / 20 (20.00%)
occurrences (all)	5	6	4
ARTHRALGIA			
subjects affected / exposed	4 / 35 (11.43%)	8 / 19 (42.11%)	2 / 20 (10.00%)
occurrences (all)	4	11	3
ARTHRITIS			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
BONE PAIN			
subjects affected / exposed	0 / 35 (0.00%)	2 / 19 (10.53%)	2 / 20 (10.00%)
occurrences (all)	0	2	2
FLANK PAIN			
subjects affected / exposed	1 / 35 (2.86%)	1 / 19 (5.26%)	1 / 20 (5.00%)
occurrences (all)	1	1	1
GROIN PAIN			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
INTERVERTEBRAL DISC PROTRUSION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
JOINT RANGE OF MOTION DECREASED			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
JOINT SWELLING			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUSCLE DISORDER			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	5 / 35 (14.29%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	6	1	0
MUSCLE TIGHTNESS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUSCULAR WEAKNESS			
subjects affected / exposed	2 / 35 (5.71%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
MUSCULOSKELETAL DISCOMFORT			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
MUSCULOSKELETAL STIFFNESS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MYALGIA			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
NECK PAIN			
subjects affected / exposed	1 / 35 (2.86%)	1 / 19 (5.26%)	1 / 20 (5.00%)
occurrences (all)	1	1	1
OSTEONECROSIS OF JAW			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PAIN IN EXTREMITY			
subjects affected / exposed	1 / 35 (2.86%)	1 / 19 (5.26%)	2 / 20 (10.00%)
occurrences (all)	2	1	2
PAIN IN JAW			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SPINAL PAIN			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	2 / 35 (5.71%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	2	0	1
NASOPHARYNGITIS			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	3	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	2 / 35 (5.71%)	0 / 19 (0.00%)	3 / 20 (15.00%)
occurrences (all)	2	0	3
URINARY TRACT INFECTION			
subjects affected / exposed	2 / 35 (5.71%)	4 / 19 (21.05%)	2 / 20 (10.00%)
occurrences (all)	2	5	2
BACTERAEMIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CANDIDA INFECTION			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
CATHETER SITE INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CELLULITIS			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVITIS			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
CONJUNCTIVITIS VIRAL			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CYSTITIS			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
CYTOMEGALOVIRUS INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DIENTAMOEBA INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
EAR INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
ERYTHEMA INDURATUM			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
FUNGAL INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FUNGAL SKIN INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FURUNCLE			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GASTROINTESTINAL VIRAL INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
GINGIVITIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GROIN ABSCESS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HERPES ZOSTER			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HORDEOLUM			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
LARYNGITIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
LOCALISED INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MASTITIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUCOSAL INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NAIL INFECTION			

subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ORAL HERPES			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PARONYCHIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
PNEUMONIA			
subjects affected / exposed	4 / 35 (11.43%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	6	0	0
PURULENT DISCHARGE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PYELONEPHRITIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY SYNCYTIAL VIRUS INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 35 (2.86%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	1	2	0
SINUSITIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN CANDIDA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

SKIN INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	1 / 20 (5.00%)
occurrences (all)	0	2	1
STOMA SITE INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TOOTH ABSCESS			
subjects affected / exposed	0 / 35 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
TOOTH INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT INFECTION BACTERIAL			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VAGINAL INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VARICELLA ZOSTER VIRUS INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VIRAL INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
VULVOVAGINAL MYCOTIC INFECTION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	11 / 35 (31.43%)	4 / 19 (21.05%)	1 / 20 (5.00%)
occurrences (all)	12	6	1

DEHYDRATION			
subjects affected / exposed	4 / 35 (11.43%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	5	1	0
ELECTROLYTE IMBALANCE			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FAILURE TO THRIVE			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
FLUID OVERLOAD			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GLUCOSE TOLERANCE IMPAIRED			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERCALCAEMIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERCHOLESTEROLAEMIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERGLYCAEMIA			
subjects affected / exposed	6 / 35 (17.14%)	1 / 19 (5.26%)	2 / 20 (10.00%)
occurrences (all)	7	1	4
HYPERKALAEMIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERMAGNESAEMIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERPHOSPHATAEMIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERTRIGLYCERIDAEMIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

HYPERURICAEMIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOALBUMINAEMIA			
subjects affected / exposed	1 / 35 (2.86%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
HYPOCALCAEMIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			
subjects affected / exposed	2 / 35 (5.71%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	3	0	1
HYPOMAGNESAEMIA			
subjects affected / exposed	3 / 35 (8.57%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	3	0	0
HYPONATRAEMIA			
subjects affected / exposed	2 / 35 (5.71%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
HYPOPHAGIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	6 / 35 (17.14%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	7	1	0
HYPOVOLAEMIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LACTIC ACIDOSIS			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MALNUTRITION			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

POLYDIPSIA			
subjects affected / exposed	0 / 35 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase I,Stage 2:Cohort N-GDC-0032 2mg QD+Letrozole 2.5mg	Phase I,Stage 2:Cohort K-GDC-0032 4mg+Fulvestrant	Phase I,Stage 2:Cohort R-GDC-0032 4mg+Letrozole 2.5mg QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	27 / 27 (100.00%)	19 / 20 (95.00%)	20 / 20 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BENIGN NEOPLASM			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BRAIN NEOPLASM			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
HAEMANGIOMA OF SKIN			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LIP NEOPLASM			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PAPILLOMA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
TUMOUR FISTULISATION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TUMOUR PAIN			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	4 / 27 (14.81%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	4	1	1
DEEP VEIN THROMBOSIS			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EMBOLISM VENOUS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
FLUSHING			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
HAEMATOMA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HOT FLUSH			
subjects affected / exposed	6 / 27 (22.22%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	6	2	0
HYPOTENSION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
JUGULAR VEIN THROMBOSIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LYMPHOEDEMA			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	2 / 27 (7.41%)	2 / 20 (10.00%)	5 / 20 (25.00%)
occurrences (all)	2	2	7
AXILLARY PAIN			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE ERYTHEMA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE INFLAMMATION			

subjects affected / exposed occurrences (all)	0 / 27 (0.00%)	0 / 20 (0.00%) 0	0 / 20 (0.00%) 0

INFLUENZA LIKE ILLNESS			
subjects affected / exposed	1 / 27 (3.70%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
INJECTION SITE ERYTHEMA			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
INJECTION SITE PAIN			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
INJECTION SITE REACTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MALAISE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUCOSAL INFLAMMATION			
subjects affected / exposed	2 / 27 (7.41%)	2 / 20 (10.00%)	1 / 20 (5.00%)
occurrences (all)	2	2	1
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	2 / 20 (10.00%)
occurrences (all)	1	0	3
OEDEMA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
OEDEMA PERIPHERAL			
subjects affected / exposed	1 / 27 (3.70%)	3 / 20 (15.00%)	1 / 20 (5.00%)
occurrences (all)	1	3	1
PAIN			
subjects affected / exposed	1 / 27 (3.70%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	1	1	3
PERIPHERAL SWELLING			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PYREXIA			
subjects affected / exposed	3 / 27 (11.11%)	1 / 20 (5.00%)	3 / 20 (15.00%)
occurrences (all)	3	3	3
XEROSIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
CONTRAST MEDIA ALLERGY			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERSENSITIVITY			
subjects affected / exposed	2 / 27 (7.41%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	3	1	0
SEASONAL ALLERGY			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
BREAST DISCHARGE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BREAST MASS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BREAST PAIN			
subjects affected / exposed	0 / 27 (0.00%)	3 / 20 (15.00%)	0 / 20 (0.00%)
occurrences (all)	0	3	0
DYSPAREUNIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
MENOPAUSAL SYMPTOMS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PELVIC PAIN			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PENILE HAEMORRHAGE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
UTERINE PAIN			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VAGINAL DISCHARGE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VAGINAL HAEMORRHAGE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VULVAL DISORDER			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL BURNING SENSATION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL DRYNESS			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
VULVOVAGINAL INFLAMMATION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL PRURITUS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
BRONCHOSPASM			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
COUGH			

subjects affected / exposed	3 / 27 (11.11%)	4 / 20 (20.00%)	4 / 20 (20.00%)
occurrences (all)	3	4	5
DYSPHONIA			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
DYSPNOEA			
subjects affected / exposed	2 / 27 (7.41%)	2 / 20 (10.00%)	5 / 20 (25.00%)
occurrences (all)	5	2	7
DYSPNOEA EXERTIONAL			
subjects affected / exposed	1 / 27 (3.70%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	1	1	1
EPISTAXIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HAEMOPTYSIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HICCUPS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOXIA			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
INCREASED UPPER AIRWAY SECRETION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INTERSTITIAL LUNG DISEASE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LARYNGEAL INFLAMMATION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LOWER RESPIRATORY TRACT CONGESTION			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LUNG CONSOLIDATION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NASAL CONGESTION			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	2 / 20 (10.00%)
occurrences (all)	1	0	2
NASAL DRYNESS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
OROPHARYNGEAL DISCOMFORT			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
PAINFUL RESPIRATION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PARANASAL SINUS DISCOMFORT			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PARANASAL SINUS HYPERSECRETION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PLEURAL EFFUSION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
PLEURITIC PAIN			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
PNEUMONIA ASPIRATION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

PNEUMONITIS			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	2	0	2
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
PULMONARY OEDEMA			
subjects affected / exposed	1 / 27 (3.70%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	1	2	0
RHINITIS ALLERGIC			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
RHINORRHOEA			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
SINUS CONGESTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
SNEEZING			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
WHEEZING			
subjects affected / exposed	2 / 27 (7.41%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Psychiatric disorders			

ANXIETY			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
DEPRESSION			
subjects affected / exposed	3 / 27 (11.11%)	1 / 20 (5.00%)	2 / 20 (10.00%)
occurrences (all)	7	1	2
AGITATION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INSOMNIA			
subjects affected / exposed	3 / 27 (11.11%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	3	1	1
LIBIDO DECREASED			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MIXED ANXIETY AND DEPRESSIVE DISORDER			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
MOOD ALTERED			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MOOD SWINGS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Investigations			
WEIGHT DECREASED			
subjects affected / exposed	2 / 27 (7.41%)	2 / 20 (10.00%)	4 / 20 (20.00%)
occurrences (all)	3	2	4
ALANINE AMINOTRANSFERASE ABNORMAL			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ALANINE AMINOTRANSFERASE INCREASED			

subjects affected / exposed	2 / 27 (7.41%)	4 / 20 (20.00%)	0 / 20 (0.00%)
occurrences (all)	3	9	0
AMYLASE INCREASED			
subjects affected / exposed	2 / 27 (7.41%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	4	0	0
ASPARTATE AMINOTRANSFERASE ABNORMAL			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	2 / 27 (7.41%)	3 / 20 (15.00%)	0 / 20 (0.00%)
occurrences (all)	3	7	0
BAND NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	1 / 27 (3.70%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
BLOOD CALCIUM DECREASED			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
BLOOD CHLORIDE DECREASED			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	0 / 27 (0.00%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	6	0
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATININE INCREASED			

subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	3	0
BLOOD INSULIN INCREASED			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD MAGNESIUM DECREASED			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
BLOOD MAGNESIUM INCREASED			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD PHOSPHORUS INCREASED			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD POTASSIUM DECREASED			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	3
BLOOD TRIGLYCERIDES INCREASED			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
BLOOD UREA INCREASED			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ELECTROCARDIOGRAM QT PROLONGED			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR INCREASED			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INTERNATIONAL NORMALISED RATIO INCREASED			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INVESTIGATION ABNORMAL			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LIPASE INCREASED			
subjects affected / exposed	2 / 27 (7.41%)	3 / 20 (15.00%)	0 / 20 (0.00%)
occurrences (all)	4	4	0
LIVER FUNCTION TEST INCREASED			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
LOW DENSITY LIPOPROTEIN INCREASED			
subjects affected / exposed	0 / 27 (0.00%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	0 / 27 (0.00%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	5	0
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
PLATELET COUNT DECREASED			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
STREPTOCOCCUS TEST POSITIVE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TROPONIN INCREASED			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
WEIGHT INCREASED			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Injury, poisoning and procedural complications			
FALL			
subjects affected / exposed	2 / 27 (7.41%)	0 / 20 (0.00%)	2 / 20 (10.00%)
occurrences (all)	2	0	2
ANIMAL BITE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BURN ORAL CAVITY			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CHEST INJURY			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CONTUSION			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
ESCHAR			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
EYE INJURY			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HIP FRACTURE			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PROCEDURAL PAIN			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RADIATION SKIN INJURY			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RIB FRACTURE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN ABRASION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN LACERATION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SPINAL COMPRESSION FRACTURE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SUNBURN			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ULNA FRACTURE			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
ANGINA PECTORIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ARRHYTHMIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

ATRIOVENTRICULAR BLOCK FIRST DEGREE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BRADYCARDIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BUNDLE BRANCH BLOCK LEFT			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LEFT VENTRICULAR FAILURE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MITRAL VALVE INCOMPETENCE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PALPITATIONS			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
SINUS TACHYCARDIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TACHYCARDIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	6 / 27 (22.22%)	3 / 20 (15.00%)	1 / 20 (5.00%)
occurrences (all)	7	3	1
HEADACHE			
subjects affected / exposed	4 / 27 (14.81%)	6 / 20 (30.00%)	5 / 20 (25.00%)
occurrences (all)	6	9	5
BALANCE DISORDER			

subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
CARPAL TUNNEL SYNDROME			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DISTURBANCE IN ATTENTION			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
DYSAESTHESIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DYSARTHRIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DYSGEUSIA			
subjects affected / exposed	3 / 27 (11.11%)	3 / 20 (15.00%)	0 / 20 (0.00%)
occurrences (all)	3	3	0
HYPERSOMNIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOAESTHESIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LETHARGY			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MEMORY IMPAIRMENT			
subjects affected / exposed	2 / 27 (7.41%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
MIGRAINE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASTICITY			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
NEURALGIA			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	2 / 27 (7.41%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	2	0	1
PARAESTHESIA			
subjects affected / exposed	2 / 27 (7.41%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	2	0	1
PAROSMIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PRESYNCOPE			
subjects affected / exposed	1 / 27 (3.70%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
SCIATICA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SEIZURE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SINUS HEADACHE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SOMNOLENCE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SYNCOPE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TASTE DISORDER			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TREMOR			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 27 (0.00%)	4 / 20 (20.00%)	2 / 20 (10.00%)
occurrences (all)	0	10	3
DISSEMINATED INTRAVASCULAR COAGULATION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
IRON DEFICIENCY ANAEMIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LEUKOPENIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LYMPHOPENIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NEUTROPENIA			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	0	1	2
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
DEAFNESS UNILATERAL			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EAR PAIN			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
EXCESSIVE CERUMEN PRODUCTION			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOACUSIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MOTION SICKNESS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TINNITUS			
subjects affected / exposed	1 / 27 (3.70%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
VERTIGO			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Eye disorders			
DIPLOPIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
DRY EYE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EXOPHTHALMOS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EYE IRRITATION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EYE PAIN			
subjects affected / exposed	1 / 27 (3.70%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	1	2	0
EYE SWELLING			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
EYELID DISORDER			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

EYELID PTOSIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GLAUCOMA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LACRIMATION INCREASED			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
OCULAR HYPERAEMIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ORBITAL OEDEMA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PERIORBITAL OEDEMA			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
PERIORBITAL SWELLING			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PHOTOPHOBIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PHOTOPSIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SCLERAL HAEMORRHAGE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
VISUAL IMPAIRMENT			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

VITREOUS FLOATERS			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Gastrointestinal disorders			
DIARRHOEA			
subjects affected / exposed	15 / 27 (55.56%)	14 / 20 (70.00%)	14 / 20 (70.00%)
occurrences (all)	29	71	23
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN			
subjects affected / exposed	5 / 27 (18.52%)	2 / 20 (10.00%)	4 / 20 (20.00%)
occurrences (all)	6	4	6
ABDOMINAL PAIN LOWER			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	3 / 27 (11.11%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	3	0	0
ABDOMINAL WALL HAEMATOMA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ANAL HAEMORRHAGE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ANORECTAL DISCOMFORT			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
APHTHOUS ULCER			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
ASCITES			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CHAPPED LIPS			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
CHEILITIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
COLITIS			
subjects affected / exposed	1 / 27 (3.70%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	3	1	1
CONSTIPATION			
subjects affected / exposed	5 / 27 (18.52%)	6 / 20 (30.00%)	4 / 20 (20.00%)
occurrences (all)	7	7	5
DENTAL CARIES			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DIVERTICULUM INTESTINAL			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DRY MOUTH			
subjects affected / exposed	3 / 27 (11.11%)	4 / 20 (20.00%)	2 / 20 (10.00%)
occurrences (all)	5	4	2
DYSPEPSIA			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	2 / 20 (10.00%)
occurrences (all)	0	1	2
DYSPHAGIA			
subjects affected / exposed	0 / 27 (0.00%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
EPIGASTRIC DISCOMFORT			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ERUCTATION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FAECES DISCOLOURED			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FLATULENCE			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
FREQUENT BOWEL MOVEMENTS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GASTRIC ULCER			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GASTRITIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	1 / 27 (3.70%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	1	1	1
GINGIVAL PAIN			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GLOSSITIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GLOSSODYNIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HAEMATOCHEZIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HAEMORRHOIDS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
HYPERCHLORHYDRIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

RFFXUUHQFHV DOO

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VXEMHFWV DIIHFWHG H[SRVHG
RFFXUUHQFHV DOO

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VXEMHFWV DIIHFWHG H[SRVHG
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VXEMHFWV DIIHFWHG H[SRVHG
RFFXUUHQFHV DOO

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VXEMHFWV DIIHFWHG H[SRVHG
RFFXUUHQFHV DOO

3$5$(67+(6,$ 25$/
VXEMHFWV DIIHFWHG H[SRVHG
RFFXUUHQFHV DOO

PERIODONTAL DISEASE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PROCTALGIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PROCTITIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RECTAL TENESMUS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RETCHING			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	6 / 27 (22.22%)	5 / 20 (25.00%)	3 / 20 (15.00%)
occurrences (all)	12	7	4
TOOTHACHE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VARICOSE VEINS SUBLINGUAL			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VOMITING			
subjects affected / exposed	7 / 27 (25.93%)	2 / 20 (10.00%)	3 / 20 (15.00%)
occurrences (all)	8	6	3
Hepatobiliary disorders			
HEPATIC PAIN			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERBILIRUBINAEMIA			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
RASH			
subjects affected / exposed	5 / 27 (18.52%)	4 / 20 (20.00%)	1 / 20 (5.00%)
occurrences (all)	10	5	1
ALOPECIA			
subjects affected / exposed	5 / 27 (18.52%)	1 / 20 (5.00%)	2 / 20 (10.00%)
occurrences (all)	6	1	2
BLISTER			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
COLD SWEAT			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DECUBITUS ULCER			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DERMATITIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DERMATITIS ACNEIFORM			
subjects affected / exposed	1 / 27 (3.70%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	1	3	0
DERMATITIS ALLERGIC			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DERMATITIS EXFOLIATIVE GENERALISED			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
DRY SKIN			
subjects affected / exposed	1 / 27 (3.70%)	2 / 20 (10.00%)	1 / 20 (5.00%)
occurrences (all)	1	2	1
DYSHIDROTIC ECZEMA			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ECCHYMOSIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ECZEMA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ECZEMA ASTEATOTIC			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ERYTHEMA			
subjects affected / exposed	0 / 27 (0.00%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
EXFOLIATIVE RASH			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERHIDROSIS			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
INGROWING NAIL			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NAIL DISCOLOURATION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NAIL DISORDER			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
NAIL DYSTROPHY			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NIGHT SWEATS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
ONYCHOCLASIS			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ONYCHOLYSIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ONYCHOMADESIS			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
PAIN OF SKIN			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PAPULE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PHOTOSENSITIVITY REACTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
PRURITUS			
subjects affected / exposed	3 / 27 (11.11%)	4 / 20 (20.00%)	1 / 20 (5.00%)
occurrences (all)	4	5	2
PRURITUS ALLERGIC			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PSORIASIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RASH MACULAR			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

RASH MACULO-PAPULAR			
subjects affected / exposed	2 / 27 (7.41%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	5	2	0
RASH PAPULAR			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RASH VESICULAR			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
ROSACEA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SEBORRHOEIC DERMATITIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN EXFOLIATION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN FISSURES			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN HYPERPIGMENTATION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN PLAQUE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN TIGHTNESS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN ULCER			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URTICARIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
AZOTAEMIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLADDER DISCOMFORT			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLADDER SPASM			
subjects affected / exposed	1 / 27 (3.70%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
CHROMATURIA			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
CYSTITIS NONINFECTIVE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DYSURIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HAEMATURIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYDRONEPHROSIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MICTURITION URGENCY			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
POLLAKIURIA			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
POLYURIA			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PROTEINURIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RENAL FAILURE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URETERIC OBSTRUCTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URETERIC STENOSIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URINARY HESITATION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URINARY RETENTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT PAIN			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	7 / 27 (25.93%)	4 / 20 (20.00%)	4 / 20 (20.00%)
occurrences (all)	7	4	4
ARTHRALGIA			
subjects affected / exposed	7 / 27 (25.93%)	5 / 20 (25.00%)	7 / 20 (35.00%)
occurrences (all)	11	7	10
ARTHRITIS			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BONE PAIN			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	3 / 20 (15.00%)
occurrences (all)	3	0	5
FLANK PAIN			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
GROIN PAIN			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
INTERVERTEBRAL DISC PROTRUSION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
JOINT RANGE OF MOTION DECREASED			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
JOINT SWELLING			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUSCLE DISORDER			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	5 / 27 (18.52%)	3 / 20 (15.00%)	2 / 20 (10.00%)
occurrences (all)	7	3	2
MUSCLE TIGHTNESS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
MUSCULOSKELETAL CHEST PAIN			

subjects affected / exposed	0 / 27 (0.00%)	2 / 20 (10.00%)	3 / 20 (15.00%)
occurrences (all)	0	2	3
MUSCULOSKELETAL DISCOMFORT			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
MUSCULOSKELETAL STIFFNESS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MYALGIA			
subjects affected / exposed	2 / 27 (7.41%)	3 / 20 (15.00%)	5 / 20 (25.00%)
occurrences (all)	3	3	6
NECK PAIN			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
OSTEONECROSIS OF JAW			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PAIN IN EXTREMITY			
subjects affected / exposed	5 / 27 (18.52%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	5	1	1
PAIN IN JAW			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
SPINAL PAIN			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
NASOPHARYNGITIS			
subjects affected / exposed	1 / 27 (3.70%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	1	8	0

UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
URINARY TRACT INFECTION			
subjects affected / exposed	4 / 27 (14.81%)	3 / 20 (15.00%)	4 / 20 (20.00%)
occurrences (all)	6	4	4
BACTERAEMIA			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
CANDIDA INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
CATHETER SITE INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CELLULITIS			
subjects affected / exposed	1 / 27 (3.70%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVITIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVITIS VIRAL			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CYSTITIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
CYTOMEGALOVIRUS INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DEVICE RELATED INFECTION			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
DIENTAMOEBA INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EAR INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
ERYTHEMA INDURATUM			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FUNGAL INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FUNGAL SKIN INFECTION			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
FURUNCLE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GASTROINTESTINAL VIRAL INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GINGIVITIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GROIN ABSCESS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HERPES ZOSTER			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
HORDEOLUM			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

LARYNGITIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LOCALISED INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MASTITIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUCOSAL INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PYELONEPHRITIS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY SYNCYTIAL VIRUS INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
SINUSITIS			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	3	0
SKIN CANDIDA			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
SKIN INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
STOMA SITE INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TOOTH ABSCESS			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TOOTH INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
URINARY TRACT INFECTION BACTERIAL			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VAGINAL INFECTION			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
VARICELLA ZOSTER VIRUS INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VIRAL INFECTION			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL MYCOTIC INFECTION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	8 / 27 (29.63%)	3 / 20 (15.00%)	8 / 20 (40.00%)
occurrences (all)	11	7	14
DEHYDRATION			
subjects affected / exposed	2 / 27 (7.41%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	3	1	1
ELECTROLYTE IMBALANCE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
FAILURE TO THRIVE			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
FLUID OVERLOAD			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
GLUCOSE TOLERANCE IMPAIRED			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERCALCAEMIA			

subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	2
HYPERCHOLESTEROLAEMIA			
subjects affected / exposed	0 / 27 (0.00%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
HYPERGLYCAEMIA			
subjects affected / exposed	7 / 27 (25.93%)	6 / 20 (30.00%)	4 / 20 (20.00%)
occurrences (all)	17	10	5
HYPERKALAEMIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERMAGNESAEMIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERPHOSPHATAEMIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERTRIGLYCERIDAEMIA			
subjects affected / exposed	1 / 27 (3.70%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	1	6	0
HYPERURICAEMIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOALBUMINAEMIA			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
HYPOCALCAEMIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			
subjects affected / exposed	3 / 27 (11.11%)	6 / 20 (30.00%)	1 / 20 (5.00%)
occurrences (all)	5	12	1
HYPOMAGNESAEMIA			

subjects affected / exposed	1 / 27 (3.70%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
HYPONATRAEMIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOPHAGIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	1 / 27 (3.70%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
HYPOVOLAEMIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LACTIC ACIDOSIS			
subjects affected / exposed	0 / 27 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
MALNUTRITION			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
POLYDIPSIA			
subjects affected / exposed	0 / 27 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase I,Stage 2:Cohort P-GDC-0032 4mg QD+Letrozole 2.5mg	Phase I,Stage 2:Cohort Q-GDC-0032 4mg+Letrozole 2.5mg QD	Phase I,Stage 2:Cohort S-GDC-0032 4mg+Letrozole 2.5mg QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	27 / 28 (96.43%)	20 / 20 (100.00%)	19 / 20 (95.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BENIGN NEOPLASM			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BRAIN NEOPLASM			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HAEMANGIOMA OF SKIN			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LIP NEOPLASM			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PAPILLOMA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TUMOUR FISTULISATION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TUMOUR PAIN			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	4 / 28 (14.29%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	5	1	1
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EMBOLISM VENOUS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FLUSHING			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HAEMATOMA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HOT FLUSH			
subjects affected / exposed	2 / 28 (7.14%)	4 / 20 (20.00%)	3 / 20 (15.00%)
occurrences (all)	2	4	3
HYPOTENSION			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0

JUGULAR VEIN THROMBOSIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LYMPHOEDEMA			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	3 / 28 (10.71%)	4 / 20 (20.00%)	3 / 20 (15.00%)
occurrences (all)	6	7	4
AXILLARY PAIN			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
CATHETER SITE ERYTHEMA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE INFLAMMATION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE OEDEMA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE RASH			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CHEST DISCOMFORT			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CHEST PAIN			
subjects affected / exposed	1 / 28 (3.57%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
CHILLS			
subjects affected / exposed	0 / 28 (0.00%)	2 / 20 (10.00%)	2 / 20 (10.00%)
occurrences (all)	0	2	2
DEVICE RELATED THROMBOSIS			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EARLY SATIETY			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FATIGUE			
subjects affected / exposed	8 / 28 (28.57%)	7 / 20 (35.00%)	7 / 20 (35.00%)
occurrences (all)	18	9	12
GAIT DISTURBANCE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GENERALISED OEDEMA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
INJECTION SITE ERYTHEMA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE PAIN			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE REACTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MALAISE			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
MUCOSAL INFLAMMATION			
subjects affected / exposed	3 / 28 (10.71%)	2 / 20 (10.00%)	2 / 20 (10.00%)
occurrences (all)	5	3	3

MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	0	1	2
OEDEMA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
OEDEMA PERIPHERAL			
subjects affected / exposed	2 / 28 (7.14%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
PAIN			
subjects affected / exposed	2 / 28 (7.14%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	3	0	1
PERIPHERAL SWELLING			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PYREXIA			
subjects affected / exposed	3 / 28 (10.71%)	2 / 20 (10.00%)	1 / 20 (5.00%)
occurrences (all)	4	4	1
XEROSIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
CONTRAST MEDIA ALLERGY			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERSENSITIVITY			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
SEASONAL ALLERGY			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

BREAST DISCHARGE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
BREAST MASS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BREAST PAIN			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
DYSPAREUNIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MENOPAUSAL SYMPTOMS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PELVIC PAIN			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
PENILE HAEMORRHAGE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
UTERINE PAIN			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VAGINAL DISCHARGE			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
VAGINAL HAEMORRHAGE			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
VULVAL DISORDER			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL BURNING SENSATION			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL DRYNESS			
subjects affected / exposed	2 / 28 (7.14%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	3	0	0
VULVOVAGINAL INFLAMMATION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL PRURITUS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
BRONCHOSPASM			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
COUGH			
subjects affected / exposed	4 / 28 (14.29%)	5 / 20 (25.00%)	3 / 20 (15.00%)
occurrences (all)	4	5	7
DYSPHONIA			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
DYSPNOEA			
subjects affected / exposed	3 / 28 (10.71%)	4 / 20 (20.00%)	2 / 20 (10.00%)
occurrences (all)	5	4	4
DYSPNOEA EXERTIONAL			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
EPISTAXIS			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
HAEMOPTYSIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HICCUPS			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOXIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INCREASED UPPER AIRWAY SECRETION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INTERSTITIAL LUNG DISEASE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LARYNGEAL INFLAMMATION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LOWER RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LUNG CONSOLIDATION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NASAL CONGESTION			
subjects affected / exposed	5 / 28 (17.86%)	4 / 20 (20.00%)	1 / 20 (5.00%)
occurrences (all)	5	5	1
NASAL DRYNESS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL DISCOMFORT			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PARANASAL SINUS DISCOMFORT			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PARANASAL SINUS HYPERSECRETION			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
PLEURAL EFFUSION			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
PLEURITIC PAIN			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
PNEUMONIA ASPIRATION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PNEUMONITIS			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	2
PRODUCTIVE COUGH			
subjects affected / exposed	1 / 28 (3.57%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	1	1	1
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PULMONARY OEDEMA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RHINITIS ALLERGIC			
subjects affected / exposed	1 / 28 (3.57%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
RHINORRHOEA			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0

SINUS CONGESTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SNEEZING			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
WHEEZING			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
DEPRESSION			
subjects affected / exposed	1 / 28 (3.57%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	1	1	1
AGITATION			
subjects affected / exposed	1 / 28 (3.57%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
CONFUSIONAL STATE			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
INSOMNIA			
subjects affected / exposed	2 / 28 (7.14%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	2	1	1
LIBIDO DECREASED			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MIXED ANXIETY AND DEPRESSIVE DISORDER			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MOOD ALTERED			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
MOOD SWINGS			
subjects affected / exposed	1 / 28 (3.57%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Investigations			
WEIGHT DECREASED			
subjects affected / exposed	4 / 28 (14.29%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	4	5	0
ALANINE AMINOTRANSFERASE ABNORMAL			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	8 / 28 (28.57%)	3 / 20 (15.00%)	1 / 20 (5.00%)
occurrences (all)	12	5	1
AMYLASE INCREASED			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
ASPARTATE AMINOTRANSFERASE ABNORMAL			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	6 / 28 (21.43%)	2 / 20 (10.00%)	3 / 20 (15.00%)
occurrences (all)	9	4	5
BAND NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	4 / 28 (14.29%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	4	0	1

BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
BLOOD CALCIUM DECREASED			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD CHLORIDE DECREASED			
subjects affected / exposed	2 / 28 (7.14%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
BLOOD INSULIN INCREASED			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD MAGNESIUM DECREASED			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD MAGNESIUM INCREASED			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD PHOSPHORUS INCREASED			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
BLOOD POTASSIUM DECREASED			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD TRIGLYCERIDES INCREASED			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD UREA INCREASED			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ELECTROCARDIOGRAM QT PROLONGED			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR INCREASED			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INVESTIGATION ABNORMAL			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LIPASE INCREASED			
subjects affected / exposed	4 / 28 (14.29%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	6	0	0
LIVER FUNCTION TEST INCREASED			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LOW DENSITY LIPOPROTEIN INCREASED			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	1 / 28 (3.57%)	3 / 20 (15.00%)	0 / 20 (0.00%)
occurrences (all)	1	4	0
NEUTROPHIL COUNT DECREASED			

subjects affected / exposed	1 / 28 (3.57%)	4 / 20 (20.00%)	0 / 20 (0.00%)
occurrences (all)	1	5	0
PLATELET COUNT DECREASED			
subjects affected / exposed	2 / 28 (7.14%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
STREPTOCOCCUS TEST POSITIVE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TRANSAMINASES INCREASED			
subjects affected / exposed	2 / 28 (7.14%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	4	0	0
TROPONIN INCREASED			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
WEIGHT INCREASED			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	3	0	1
Injury, poisoning and procedural complications			
FALL			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ANIMAL BITE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BURN ORAL CAVITY			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CHEST INJURY			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CONTUSION			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ESCHAR			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EYE INJURY			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HIP FRACTURE			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
LIMB FRACTURE			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
LIMB INJURY			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
POST PROCEDURAL HAEMORRHAGE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PROCEDURAL PAIN			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RADIATION SKIN INJURY			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
RIB FRACTURE			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
SKIN ABRASION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN LACERATION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SPINAL COMPRESSION FRACTURE			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SUNBURN			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ULNA FRACTURE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
ANGINA PECTORIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ARRHYTHMIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ATRIOVENTRICULAR BLOCK FIRST DEGREE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BRADYCARDIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BUNDLE BRANCH BLOCK LEFT			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LEFT VENTRICULAR FAILURE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MITRAL VALVE INCOMPETENCE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PALPITATIONS			

subjects affected / exposed	1 / 28 (3.57%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
SINUS TACHYCARDIA			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TACHYCARDIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	5 / 28 (17.86%)	5 / 20 (25.00%)	3 / 20 (15.00%)
occurrences (all)	6	6	3
HEADACHE			
subjects affected / exposed	4 / 28 (14.29%)	8 / 20 (40.00%)	5 / 20 (25.00%)
occurrences (all)	4	10	7
BALANCE DISORDER			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CARPAL TUNNEL SYNDROME			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DISTURBANCE IN ATTENTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DYSAESTHESIA			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
DYSARTHRIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DYSGEUSIA			
subjects affected / exposed	2 / 28 (7.14%)	2 / 20 (10.00%)	2 / 20 (10.00%)
occurrences (all)	2	2	2

HYPERSOMNIA			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
HYPOAESTHESIA			
subjects affected / exposed	1 / 28 (3.57%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
LETHARGY			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
MEMORY IMPAIRMENT			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
MIGRAINE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASTICITY			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NEURALGIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PARAESTHESIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	2
PAROSMIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	2 / 28 (7.14%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	3	1	0
PRESYNCOPE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

SCIATICA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SEIZURE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SINUS HEADACHE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SOMNOLENCE			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
SYNCOPE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TASTE DISORDER			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
TREMOR			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	2 / 28 (7.14%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	4	2	0
DISSEMINATED INTRAVASCULAR COAGULATION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
IRON DEFICIENCY ANAEMIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LEUKOPENIA			

subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
LYMPHOPENIA			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)		8	1

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DRY EYE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EXOPHTHALMOS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EYE IRRITATION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EYE PAIN			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EYE SWELLING			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EYELID DISORDER			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EYELID PTOSIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GLAUCOMA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LACRIMATION INCREASED			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
OCULAR HYPERAEMIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ORBITAL OEDEMA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PERIORBITAL OEDEMA			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PERIORBITAL SWELLING			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PHOTOPHOBIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
PHOTOPSIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SCLERAL HAEMORRHAGE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
subjects affected / exposed	2 / 28 (7.14%)	2 / 20 (10.00%)	1 / 20 (5.00%)
occurrences (all)	2	2	1
VISUAL IMPAIRMENT			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
VITREOUS FLOATERS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
DIARRHOEA			
subjects affected / exposed	20 / 28 (71.43%)	10 / 20 (50.00%)	8 / 20 (40.00%)
occurrences (all)	82	27	11
ABDOMINAL DISCOMFORT			
subjects affected / exposed	2 / 28 (7.14%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	2	0	1
ABDOMINAL DISTENSION			
subjects affected / exposed	5 / 28 (17.86%)	4 / 20 (20.00%)	3 / 20 (15.00%)
occurrences (all)	8	4	3
ABDOMINAL PAIN			
subjects affected / exposed	5 / 28 (17.86%)	4 / 20 (20.00%)	5 / 20 (25.00%)
occurrences (all)	7	4	7

ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	1 / 28 (3.57%)	2 / 20 (10.00%)	1 / 20 (5.00%)
occurrences (all)	1	2	1
ABDOMINAL WALL HAEMATOMA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ANAL HAEMORRHAGE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ANORECTAL DISCOMFORT			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
APHTHOUS ULCER			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ASCITES			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CHAPPED LIPS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CHEILITIS			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
COLITIS			
subjects affected / exposed	2 / 28 (7.14%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
CONSTIPATION			
subjects affected / exposed	4 / 28 (14.29%)	4 / 20 (20.00%)	2 / 20 (10.00%)
occurrences (all)	5	4	2
DENTAL CARIES			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

DIVERTICULUM INTESTINAL			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DRY MOUTH			
subjects affected / exposed	2 / 28 (7.14%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	2	0	1
DYSPEPSIA			
subjects affected / exposed	2 / 28 (7.14%)	1 / 20 (5.00%)	2 / 20 (10.00%)
occurrences (all)	2	1	2
DYSPHAGIA			
subjects affected / exposed	2 / 28 (7.14%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
EPIGASTRIC DISCOMFORT			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ERUCTATION			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
FAECES DISCOLOURED			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FLATULENCE			
subjects affected / exposed	3 / 28 (10.71%)	1 / 20 (5.00%)	2 / 20 (10.00%)
occurrences (all)	4	1	3
FREQUENT BOWEL MOVEMENTS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GASTRIC ULCER			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GASTRITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			

subjects affected / exposed	6 / 28 (21.43%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	6	0	1
GINGIVAL PAIN			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GLOSSITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GLOSSODYNIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HAEMATOCHEZIA			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
HAEMORRHOIDS			
subjects affected / exposed	3 / 28 (10.71%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	4	0	0
HYPERCHLORHYDRIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOAESTHESIA ORAL			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LARGE INTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LIP PAIN			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MESENTERIC ARTERY THROMBOSIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MOUTH ULCERATION			
subjects affected / exposed	2 / 28 (7.14%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
NAUSEA			

subjects affected / exposed	17 / 28 (60.71%)	8 / 20 (40.00%)	7 / 20 (35.00%)
occurrences (all)	25	10	7
ODYNOPHAGIA			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
OESOPHAGEAL PAIN			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
OESOPHAGITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ORAL DYSAESTHESIA			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
ORAL PAIN			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
PARAESTHESIA ORAL			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PERIODONTAL DISEASE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PROCTALGIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PROCTITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RECTAL HAEMORRHAGE			
subjects affected / exposed	2 / 28 (7.14%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
RECTAL TENESMUS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RETCHING			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	9 / 28 (32.14%)	4 / 20 (20.00%)	3 / 20 (15.00%)
occurrences (all)	16	8	3
TOOTHACHE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VARICOSE VEINS SUBLINGUAL			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VOMITING			
subjects affected / exposed	5 / 28 (17.86%)	4 / 20 (20.00%)	4 / 20 (20.00%)
occurrences (all)	15	4	9
Hepatobiliary disorders			
HEPATIC PAIN			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
RASH			
subjects affected / exposed	4 / 28 (14.29%)	3 / 20 (15.00%)	1 / 20 (5.00%)
occurrences (all)	7	8	1
ALOPECIA			
subjects affected / exposed	5 / 28 (17.86%)	2 / 20 (10.00%)	1 / 20 (5.00%)
occurrences (all)	6	2	1
BLISTER			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
COLD SWEAT			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DECUBITUS ULCER			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DERMATITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DERMATITIS ACNEIFORM			
subjects affected / exposed	2 / 28 (7.14%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	2	3	0
DERMATITIS ALLERGIC			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
DERMATITIS EXFOLIATIVE GENERALISED			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DRY SKIN			
subjects affected / exposed	5 / 28 (17.86%)	3 / 20 (15.00%)	1 / 20 (5.00%)
occurrences (all)	6	3	1
DYSHIDROTIC ECZEMA			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
ECCHYMOSIS			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
ECZEMA			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
ECZEMA ASTEATOTIC			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ERYTHEMA			
subjects affected / exposed	1 / 28 (3.57%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
EXFOLIATIVE RASH			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

HYPERHIDROSIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
INGROWING NAIL			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NAIL DISCOLOURATION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NAIL DISORDER			
subjects affected / exposed	2 / 28 (7.14%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
NAIL DYSTROPHY			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NIGHT SWEATS			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
ONYCHOCLASIS			
subjects affected / exposed	2 / 28 (7.14%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
ONYCHOLYSIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ONYCHOMADESIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PAIN OF SKIN			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
PAPULE			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PHOTOSENSITIVITY REACTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PRURITUS			
subjects affected / exposed	4 / 28 (14.29%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	7	0	1
PRURITUS ALLERGIC			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PSORIASIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RASH ERYTHEMATOUS			
subjects affected / exposed	1 / 28 (3.57%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	4	2	0
RASH MACULAR			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RASH MACULO-PAPULAR			
subjects affected / exposed	4 / 28 (14.29%)	1 / 20 (5.00%)	3 / 20 (15.00%)
occurrences (all)	10	1	4
RASH PAPULAR			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RASH VESICULAR			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ROSACEA			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
SEBORRHOEIC DERMATITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN EXFOLIATION			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN FISSURES			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN HYPERPIGMENTATION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN PLAQUE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN TIGHTNESS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN ULCER			
subjects affected / exposed	1 / 28 (3.57%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
URTICARIA			
subjects affected / exposed		0 / 20 (0.00%)	0 / 20 (0.00%)

CYSTITIS NONINFECTIVE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DYSURIA			
subjects affected / exposed	2 / 28 (7.14%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
HAEMATURIA			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
HYDRONEPHROSIS			
subjects affected / exposed	0 / 28 (0.00%)	2 / 20 (10.00%)	1 / 20 (5.00%)
occurrences (all)	0	2	1
MICTURITION URGENCY			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
POLLAKIURIA			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
POLYURIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PROTEINURIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
RENAL FAILURE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URETERIC OBSTRUCTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URETERIC STENOSIS			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
URINARY HESITATION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

URINARY RETENTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT PAIN			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	4 / 28 (14.29%)	5 / 20 (25.00%)	3 / 20 (15.00%)
occurrences (all)	5	6	5
ARTHRALGIA			
subjects affected / exposed	10 / 28 (35.71%)	8 / 20 (40.00%)	5 / 20 (25.00%)
occurrences (all)	21	8	7
ARTHRITIS			
subjects affected / exposed	1 / 28 (3.57%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	1	2	0
BONE PAIN			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	4 / 20 (20.00%)
occurrences (all)	0	1	4
FLANK PAIN			
subjects affected / exposed	0 / 28 (0.00%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
GROIN PAIN			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INTERVERTEBRAL DISC PROTRUSION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
JOINT RANGE OF MOTION DECREASED			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
JOINT SWELLING			

subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
MUSCLE DISORDER			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	2 / 28 (7.14%)	5 / 20 (25.00%)	2 / 20 (10.00%)
occurrences (all)	3	5	2
MUSCLE TIGHTNESS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUSCULAR WEAKNESS			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	4 / 28 (14.29%)	1 / 20 (5.00%)	3 / 20 (15.00%)
occurrences (all)	4	1	3
MUSCULOSKELETAL DISCOMFORT			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	1 / 28 (3.57%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	3	3	0
MUSCULOSKELETAL STIFFNESS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MYALGIA			
subjects affected / exposed	5 / 28 (17.86%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	6	1	2
NECK PAIN			
subjects affected / exposed	2 / 28 (7.14%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	2	1	1
OSTEONECROSIS OF JAW			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PAIN IN EXTREMITY			

subjects affected / exposed	1 / 28 (3.57%)	1 / 20 (5.00%)	2 / 20 (10.00%)
occurrences (all)	1	1	5
PAIN IN JAW			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
SPINAL PAIN			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NASOPHARYNGITIS			
subjects affected / exposed	0 / 28 (0.00%)	4 / 20 (20.00%)	0 / 20 (0.00%)
occurrences (all)	0	5	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	4 / 28 (14.29%)	4 / 20 (20.00%)	1 / 20 (5.00%)
occurrences (all)	5	6	1
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 28 (3.57%)	2 / 20 (10.00%)	1 / 20 (5.00%)
occurrences (all)	1	2	1
BACTERAEMIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CANDIDA INFECTION			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
CATHETER SITE INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
CELLULITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CLOSTRIDIUM DIFFICILE INFECTION			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVITIS			
subjects affected / exposed	1 / 28 (3.57%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
CONJUNCTIVITIS VIRAL			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CYSTITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CYTOMEGALOVIRUS INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
DIENTAMOEBA INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EAR INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
ERYTHEMA INDURATUM			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FUNGAL INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FUNGAL SKIN INFECTION			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
FURUNCLE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GASTROINTESTINAL VIRAL			

INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GINGIVITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GROIN ABSCESS			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
HERPES ZOSTER			
subjects affected / exposed	1 / 28 (3.57%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
HORDEOLUM			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LARYNGITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LOCALISED INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
MASTITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	2
MUCOSAL INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NAIL INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
ORAL CANDIDIASIS			

subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ORAL HERPES			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
PARONYCHIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
PURULENT DISCHARGE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PYELONEPHRITIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY SYNCYTIAL VIRUS INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SINUSITIS			
subjects affected / exposed	1 / 28 (3.57%)	1 / 20 (5.00%)	2 / 20 (10.00%)
occurrences (all)	1	1	2
SKIN CANDIDA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

STOMA SITE INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TOOTH ABSCESS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TOOTH INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT INFECTION BACTERIAL			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VAGINAL INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VARICELLA ZOSTER VIRUS INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VIRAL INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
VULVOVAGINAL MYCOTIC INFECTION			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	5 / 28 (17.86%)	7 / 20 (35.00%)	3 / 20 (15.00%)
occurrences (all)	6	8	4
DEHYDRATION			
subjects affected / exposed	3 / 28 (10.71%)	3 / 20 (15.00%)	1 / 20 (5.00%)
occurrences (all)	3	3	1

ELECTROLYTE IMBALANCE			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FAILURE TO THRIVE			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
FLUID OVERLOAD			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GLUCOSE TOLERANCE IMPAIRED			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
HYPERCALCAEMIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
HYPERCHOLESTEROLAEMIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERGLYCAEMIA			
subjects affected / exposed	11 / 28 (39.29%)	5 / 20 (25.00%)	4 / 20 (20.00%)
occurrences (all)	29	12	5
HYPERKALAEMIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERMAGNESAEMIA			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
HYPERPHOSPHATAEMIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
HYPERTRIGLYCERIDAEMIA			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
HYPERURICAEMIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

HYPOALBUMINAEMIA			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
HYPOCALCAEMIA			
subjects affected / exposed	2 / 28 (7.14%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	3	0	0
HYPOGLYCAEMIA			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
HYPOKALAEMIA			
subjects affected / exposed	2 / 28 (7.14%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	3	1	1
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 28 (0.00%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	0	1	2
HYPONATRAEMIA			
subjects affected / exposed	1 / 28 (3.57%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
HYPOPHAGIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	2 / 28 (7.14%)	3 / 20 (15.00%)	1 / 20 (5.00%)
occurrences (all)	3	3	1
HYPOVOLAEMIA			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LACTIC ACIDOSIS			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MALNUTRITION			
subjects affected / exposed	0 / 28 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
POLYDIPSIA			
subjects affected / exposed	1 / 28 (3.57%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	1	1	0

Non-serious adverse events	Phase I, Stage 2: Cohort T - GDC-0032 4 mg QD	Phase I, Stage 2: Cohort T2 - GDC-0032 4 mg QD	Phase I, Stage 2: Cohort X - GDC-0032 4 mg QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 10 (100.00%)	10 / 10 (100.00%)	69 / 70 (98.57%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BENIGN NEOPLASM			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
BRAIN NEOPLASM			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
HAEMANGIOMA OF SKIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
LIP NEOPLASM			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
PAPILLOMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
TUMOUR FISTULISATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
TUMOUR PAIN			
subjects affected / exposed	0 / 10 (0.00%)	2 / 10 (20.00%)	2 / 70 (2.86%)
occurrences (all)	0	2	2
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences (all)	0	0	2
DEEP VEIN THR		VEIN R	

FLUSHING			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
HAEMATOMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
HOT FLUSH			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
HYPOTENSION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	4 / 70 (5.71%)
occurrences (all)	0	0	6
JUGULAR VEIN THROMBOSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
LYMPHOEDEMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences (all)	0	0	3
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	6 / 10 (60.00%)	2 / 10 (20.00%)	8 / 70 (11.43%)
occurrences (all)	12	2	22
AXILLARY PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE ERYTHEMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE INFLAMMATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE OEDEMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE RASH			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
CHEST DISCOMFORT			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
CHEST PAIN			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	1	0	0
CHILLS			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	5 / 70 (7.14%)
occurrences (all)	1	0	8
DEVICE RELATED THROMBOSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
EARLY SATIETY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
FATIGUE			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	25 / 70 (35.71%)
occurrences (all)	0	1	40
GAIT DISTURBANCE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
GENERALISED OEDEMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE ERYTHEMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0

INJECTION SITE PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE REACTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
MALAISE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	6 / 70 (8.57%)
occurrences (all)	0	0	6
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 70 (0.00%)
occurrences (all)	0	1	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	2
OEDEMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	10 / 70 (14.29%)
occurrences (all)	0	0	14
PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	5 / 70 (7.14%)
occurrences (all)	0	0	5
PERIPHERAL SWELLING			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
PYREXIA			
subjects affected / exposed	4 / 10 (40.00%)	0 / 10 (0.00%)	10 / 70 (14.29%)
occurrences (all)	6	0	15
XEROSIS			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
CONTRAST MEDIA ALLERGY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
HYPERSENSITIVITY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
SEASONAL ALLERGY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
BREAST DISCHARGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
BREAST MASS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
BREAST PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
DYSPAREUNIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
MENOPAUSAL SYMPTOMS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
PELVIC PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
PENILE HAEMORRHAGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
UTERINE PAIN			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
VAGINAL DISCHARGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
VAGINAL HAEMORRHAGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences (all)	0	0	2
VULVAL DISORDER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL BURNING SENSATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL DRYNESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences (all)	0	0	3
VULVOVAGINAL INFLAMMATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL PRURITUS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
BRONCHOSPASM			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	1	0	0
COUGH			
subjects affected / exposed	1 / 10 (10.00%)	1 / 10 (10.00%)	13 / 70 (18.57%)
occurrences (all)	1	1	15
DYSPHONIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences (all)	0	0	2
DYSPNOEA			

subjects affected / exposed	0 / 10 (0.00%)	2 / 10 (20.00%)	10 / 70 (14.29%)
occurrences (all)	0	2	11
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences (all)	0	0	2
EPISTAXIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
HAEMOPTYSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
HICCUPS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
HYPOXIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	2
INCREASED UPPER AIRWAY SECRETION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
INTERSTITIAL LUNG DISEASE			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 70 (0.00%)
occurrences (all)	0	1	0
LARYNGEAL INFLAMMATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
LOWER RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
LUNG CONSOLIDATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
NASAL CONGESTION			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	6 / 70 (8.57%)
occurrences (all)	0	0	6
NASAL DRYNESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL DISCOMFORT			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
PAINFUL RESPIRATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
PARANASAL SINUS DISCOMFORT			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
PARANASAL SINUS HYPERSECRETION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
PLEURAL EFFUSION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences (all)	0	0	2
PLEURITIC PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
PNEUMONIA ASPIRATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
PNEUMONITIS			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	5 / 70 (7.14%)
occurrences (all)	1	0	5
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	3 / 70 (4.29%)
occurrences (all)	0	0	3

PULMONARY EMBOLISM			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
PULMONARY OEDEMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
RHINITIS ALLERGIC			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
RHINORRHOEA			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	1	0	0
SINUS CONGESTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
SNEEZING			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
WHEEZING			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences (all)	0	0	2
DEPRESSION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
AGITATION			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
INSOMNIA			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	3 / 70 (4.29%)
occurrences (all)	0	1	3
LIBIDO DECREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
MIXED ANXIETY AND DEPRESSIVE DISORDER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	4
MOOD ALTERED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
MOOD SWINGS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Investigations			
WEIGHT DECREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	14 / 70 (20.00%)
occurrences (all)	0	0	23
ALANINE AMINOTRANSFERASE ABNORMAL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	3 / 10 (30.00%)	1 / 10 (10.00%)	2 / 70 (2.86%)
occurrences (all)	5	1	2
AMYLASE INCREASED			
subjects affected / exposed	2 / 10 (20.00%)	1 / 10 (10.00%)	0 / 70 (0.00%)
occurrences (all)	3	2	0
ASPARTATE AMINOTRANSFERASE ABNORMAL			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	2 / 10 (20.00%)	2 / 10 (20.00%)	2 / 70 (2.86%)
occurrences (all)	3	3	2
BAND NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences (all)	0	0	2
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	2 / 10 (20.00%)	1 / 10 (10.00%)	4 / 70 (5.71%)
occurrences (all)	2	1	5
BLOOD CALCIUM DECREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
BLOOD CHLORIDE DECREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	1 / 10 (10.00%)	1 / 10 (10.00%)	1 / 70 (1.43%)
occurrences (all)	1	7	1
BLOOD CREATININE INCREASED			
subjects affected / exposed	4 / 10 (40.00%)	1 / 10 (10.00%)	6 / 70 (8.57%)
occurrences (all)	7	1	6
BLOOD INSULIN INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
BLOOD MAGNESIUM DECREASED			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
BLOOD MAGNESIUM INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
BLOOD PHOSPHORUS INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
BLOOD POTASSIUM DECREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
BLOOD TRIGLYCERIDES INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
BLOOD UREA INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
ELECTROCARDIOGRAM QT PROLONGED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
INVESTIGATION ABNORMAL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
LIPASE INCREASED			

subjects affected / exposed	1 / 10 (10.00%)	1 / 10 (10.00%)	0 / 70 (0.00%)
occurrences (all)	1	1	0
LIVER FUNCTION TEST INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1

FALL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	4 / 70 (5.71%)
occurrences (all)	0	0	5
ANIMAL BITE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
BURN ORAL CAVITY			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	1	0	0
CHEST INJURY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
CONTUSION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
ESCHAR			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
EYE INJURY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
HIP FRACTURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
LIMB FRACTURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
LIMB INJURY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
POST PROCEDURAL HAEMORRHAGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
PROCEDURAL PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0

RADIATION SKIN INJURY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
RIB FRACTURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
SKIN ABRASION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
SKIN LACERATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
SPINAL COMPRESSION FRACTURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
SUNBURN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
ULNA FRACTURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
ANGINA PECTORIS			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 70 (0.00%)
occurrences (all)	0	1	0
ARRHYTHMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
ATRIOVENTRICULAR BLOCK FIRST DEGREE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
BRADYCARDIA			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
BUNDLE BRANCH BLOCK LEFT			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
LEFT VENTRICULAR FAILURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
MITRAL VALVE INCOMPETENCE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
PALPITATIONS			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	1 / 70 (1.43%)
occurrences (all)	0	1	1
SINUS TACHYCARDIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
TACHYCARDIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	9 / 70 (12.86%)
occurrences (all)	0	0	11
HEADACHE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	6 / 70 (8.57%)
occurrences (all)	0	0	10
BALANCE DISORDER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
CARPAL TUNNEL SYNDROME			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	1	0	0

DISTURBANCE IN ATTENTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
DYSAESTHESIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
DYSARTHRIA			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 70 (0.00%)
occurrences (all)	0	1	0
DYSGEUSIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences (all)	0	0	5
HYPERSOMNIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
HYPOAESTHESIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
LETHARGY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
MEMORY IMPAIRMENT			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
MIGRAINE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASTICITY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
NEURALGIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 70 (0.00%)
occurrences (all)	0	1	0

PARAESTHESIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
PAROSMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
PRESYNCOPE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
SCIATICA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
SEIZURE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
SINUS HEADACHE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
SOMNOLENCE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
SYNCOPE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
TASTE DISORDER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
TREMOR			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
ANAEMIA			

subjects affected / exposed	5 / 10 (50.00%)	0 / 10 (0.00%)	4 / 70 (5.71%)
occurrences (all)	11	0	6
DISSEMINATED INTRAVASCULAR COAGULATION			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 70 (0.00%)
occurrences (all)	0	1	0
FEBRILE NEUTROPENIA			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	1	0	0
IRON DEFICIENCY ANAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
LEUKOPENIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
LYMPHOPENIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
NEUTROPENIA			
subjects affected / exposed	4 / 10 (40.00%)	3 / 10 (30.00%)	3 / 70 (4.29%)
occurrences (all)	10	5	5
THROMBOCYTOPENIA			
subjects affected / exposed	6 / 10 (60.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	30	0	0
Ear and labyrinth disorders			
DEAFNESS UNILATERAL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
EAR PAIN			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	1	0	0
EXCESSIVE CERUMEN PRODUCTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
HYPOACUSIS			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
MOTION SICKNESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
TINNITUS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
VERTIGO			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences (all)	0	0	2
Eye disorders			
DIPLOPIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
DRY EYE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
EXOPHTHALMOS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
EYE IRRITATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
EYE PAIN			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	1	0	0
EYE SWELLING			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
EYELID DISORDER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
EYELID PTOSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0

GLAUCOMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
LACRIMATION INCREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
OCULAR HYPERAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
ORBITAL OEDEMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
PERIORBITAL OEDEMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
PERIORBITAL SWELLING			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
PHOTOPHOBIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
PHOTOPSIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
SCLERAL HAEMORRHAGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences (all)	0	0	2
VISUAL IMPAIRMENT			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
VITREOUS FLOATERS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0

Gastrointestinal disorders			
DIARRHOEA			
subjects affected / exposed	6 / 10 (60.00%)	5 / 10 (50.00%)	33 / 70 (47.14%)
occurrences (all)	9	7	73
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	7 / 70 (10.00%)
occurrences (all)	0	0	8
ABDOMINAL PAIN			
subjects affected / exposed	2 / 10 (20.00%)	0 / 10 (0.00%)	16 / 70 (22.86%)
occurrences (all)	2	0	25
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences (all)	0	0	2
ABDOMINAL PAIN UPPER			
subjects affected / exposed	2 / 10 (20.00%)	1 / 10 (10.00%)	4 / 70 (5.71%)
occurrences (all)	2	1	4
ABDOMINAL WALL HAEMATOMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
ANAL HAEMORRHAGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
ANORECTAL DISCOMFORT			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
APHTHOUS ULCER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
ASCITES			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences (all)	0	0	2
CHAPPED LIPS			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
CHEILITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
COLITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	4 / 70 (5.71%)
occurrences (all)	0	0	5
CONSTIPATION			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	10 / 70 (14.29%)
occurrences (all)	1	0	13
DENTAL CARIES			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
DIVERTICULUM INTESTINAL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
DRY MOUTH			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	3 / 70 (4.29%)
occurrences (all)	0	0	3
DYSPEPSIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences (all)	0	0	3
DYSPHAGIA			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	1	0	1
EPIGASTRIC DISCOMFORT			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
ERUCTATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
FAECES DISCOLOURED			
subjects affected / exposed			0 / 70 (0.00%)

subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences (all)	1	0	2
FREQUENT BOWEL MOVEMENTS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
GASTRIC ULCER			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 70 (0.00%)
occurrences (all)	0	1	0
GASTRITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	4 / 70 (5.71%)
occurrences (all)	0	1	4
GINGIVAL PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
GLOSSITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
GLOSSODYNIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
HAEMATOCHEZIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
HAEMORRHOIDS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
HYPERCHLORHYDRIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
HYPOAESTHESIA ORAL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0

LARGE INTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
LIP PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
MESENTERIC ARTERY THROMBOSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
MOUTH ULCERATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	2
NAUSEA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	24 / 70 (34.29%)
occurrences (all)	0	0	33
ODYNOPHAGIA			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	1	0	0
OESOPHAGEAL PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
OESOPHAGITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
ORAL DYSAESTHESIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
ORAL PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
PARAESTHESIA ORAL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
PERIODONTAL DISEASE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0

PROCTALGIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences (all)	0	0	5
PROCTITIS			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	1	0	0
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
RECTAL TENESMUS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
RETCHING			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	6 / 70 (8.57%)
occurrences (all)	1	0	6
TOOTHACHE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	4 / 70 (5.71%)
occurrences (all)	0	0	4
VARICOSE VEINS SUBLINGUAL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
VOMITING			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	19 / 70 (27.14%)
occurrences (all)	0	0	24
Hepatobiliary disorders			
HEPATIC PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			

RASH			
subjects affected / exposed	2 / 10 (20.00%)	1 / 10 (10.00%)	9 / 70 (12.86%)
occurrences (all)	4	3	13
ALOPECIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
BLISTER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
COLD SWEAT			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
DECUBITUS ULCER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
DERMATITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
DERMATITIS ALLERGIC			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
DERMATITIS EXFOLIATIVE GENERALISED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
DRY SKIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	7 / 70 (10.00%)
occurrences (all)	0	0	7
DYSHIDROTIC ECZEMA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
ECCHYMOSIS			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
ECZEMA			
subjects affected / exposed	1 / 10 (10.00%)	1 / 10 (10.00%)	3 / 70 (4.29%)
occurrences (all)	3	1	5
ECZEMA ASTEATOTIC			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
ERYTHEMA			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 70 (0.00%)
occurrences (all)	0	1	0
EXFOLIATIVE RASH			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	1 / 70 (1.43%)
occurrences (all)	0	1	1
INGROWING NAIL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
NAIL DISCOLOURATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
NAIL DISORDER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
NAIL DYSTROPHY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
NIGHT SWEATS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
ONYCHOCLASIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
ONYCHOLYSIS			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
ONYCHOMADESIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
PAIN OF SKIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
PAPULE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
PHOTOSENSITIVITY REACTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences (all)	0	0	3
PRURITUS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	6 / 70 (8.57%)
occurrences (all)	0	0	10
PRURITUS ALLERGIC			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
PSORIASIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
RASH MACULAR			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	5 / 70 (7.14%)
occurrences (all)	0	1	7

RASH PAPULAR			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
RASH VESICULAR			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
ROSACEA			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 70 (0.00%)
occurrences (all)	0	1	0
SEBORRHOEIC DERMATITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
SKIN EXFOLIATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
SKIN FISSURES			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
SKIN HYPERPIGMENTATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
SKIN PLAQUE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
SKIN TIGHTNESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
SKIN ULCER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
URTICARIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	3 / 70 (4.29%)
occurrences (all)	0	0	3
AZOTAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
BLADDER DISCOMFORT			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
BLADDER SPASM			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
CHROMATURIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
CYSTITIS NONINFECTIVE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
DYSURIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences (all)	0	0	2
HAEMATURIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	3 / 70 (4.29%)
occurrences (all)	0	0	5
HYDRONEPHROSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
MICTURITION URGENCY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
POLLAKIURIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
POLYURIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
PROTEINURIA			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
RENAL FAILURE			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 70 (0.00%)
occurrences (all)	0	1	0
URETERIC OBSTRUCTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
URETERIC STENOSIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
URINARY HESITATION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
URINARY RETENTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences (all)	0	0	2
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
URINARY TRACT PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	2 / 10 (20.00%)	1 / 10 (10.00%)	7 / 70 (10.00%)
occurrences (all)	2	1	8
ARTHRALGIA			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	5 / 70 (7.14%)
occurrences (all)	0	2	7
ARTHRITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
BONE PAIN			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
FLANK PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences (all)	0	0	2
GROIN PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
INTERVERTEBRAL DISC PROTRUSION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
JOINT RANGE OF MOTION DECREASED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
JOINT SWELLING			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
MUSCLE DISORDER			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 70 (0.00%)
occurrences (all)	0	1	0
MUSCLE SPASMS			
subjects affected / exposed	1 / 10 (10.00%)	2 / 10 (20.00%)	5 / 70 (7.14%)
occurrences (all)	1	2	8
MUSCLE TIGHTNESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences (all)	0	0	2
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	6 / 70 (8.57%)
occurrences (all)	0	0	6
MUSCULOSKELETAL DISCOMFORT			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
MUSCULOSKELETAL STIFFNESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
MYALGIA			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	3 / 70 (4.29%)
occurrences (all)	0	1	3
NECK PAIN			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	1	0	1
OSTEONECROSIS OF JAW			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	6 / 70 (8.57%)
occurrences (all)	0	0	6
PAIN IN JAW			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
SPINAL PAIN			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	1	0	0
NASOPHARYNGITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
UPPER RESPIRATORY TRACT INFECTION			

subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	3 / 70 (4.29%)
occurrences (all)	2	0	3
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	12 / 70 (17.14%)
occurrences (all)	1	0	17
BACTERAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
CANDIDA INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
CELLULITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences (all)	0	0	2
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	3 / 70 (4.29%)
occurrences (all)	0	0	3
CONJUNCTIVITIS			
subjects affected / exposed	1 / 10 (10.00%)	1 / 10 (10.00%)	0 / 70 (0.00%)
occurrences (all)	1	1	0
CONJUNCTIVITIS VIRAL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
CYSTITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
CYTOMEGALOVIRUS INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 70 (0.00%)
occurrences (all)	0	1	0
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
DIENTAMOEBA INFECTION			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
EAR INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
ERYTHEMA INDURATUM			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
FUNGAL INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
FUNGAL SKIN INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
FURUNCLE			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	1	0	0
GASTROINTESTINAL VIRAL INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
GINGIVITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
GROIN ABSCESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
HERPES ZOSTER			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
HORDEOLUM			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
LARYNGITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0

LOCALISED INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
MASTITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
MUCOSAL INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
NAIL INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	1	0	0
ORAL HERPES			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	1	0	1
PARONYCHIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
PHARYNGITIS			
subjects affected / exposed	1 / 10 (10.00%)	1 / 10 (10.00%)	0 / 70 (0.00%)
occurrences (all)	1	1	0
PNEUMONIA			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	3 / 70 (4.29%)
occurrences (all)	1	0	3
PURULENT DISCHARGE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
PYELONEPHRITIS			

subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 70 (0.00%)
occurrences (all)	0	1	0
RESPIRATORY SYNCYTIAL VIRUS INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	2 / 10 (20.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences (all)	2	0	2
SINUSITIS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
SKIN CANDIDA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
SKIN INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
STOMA SITE INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
TOOTH ABSCESS			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
TOOTH INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT INFECTION BACTERIAL			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
VAGINAL INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
VARICELLA ZOSTER VIRUS INFECTION			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
VIRAL INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL MYCOTIC INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	2 / 10 (20.00%)	0 / 10 (0.00%)	23 / 70 (32.86%)
occurrences (all)	3	0	41
DEHYDRATION			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	7 / 70 (10.00%)
occurrences (all)	1	0	9
ELECTROLYTE IMBALANCE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
FAILURE TO THRIVE			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
FLUID OVERLOAD			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
GLUCOSE TOLERANCE IMPAIRED			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
HYPERCALCAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 70 (0.00%)
occurrences (all)	0	1	0
HYPERCHOLESTEROLAEMIA			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
HYPERGLYCAEMIA			
subjects affected / exposed	7 / 10 (70.00%)	3 / 10 (30.00%)	14 / 70 (20.00%)
occurrences (all)	31	3	17
HYPERKALAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
HYPERMAGNESAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
HYPERPHOSPHATAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
HYPERTRIGLYCERIDAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 70 (0.00%)
occurrences (all)	0	1	0
HYPERURICAEMIA			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	1	0	0
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 70 (2.86%)
occurrences (all)	0	0	5
HYPOCALCAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 70 (0.00%)
occurrences (all)	0	1	0
HYPOKALAEMIA			
subjects affected / exposed	2 / 10 (20.00%)	0 / 10 (0.00%)	8 / 70 (11.43%)
occurrences (all)	2	0	9
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	7 / 70 (10.00%)
occurrences (all)	0	0	8
HYPONATRAEMIA			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	4 / 70 (5.71%)
occurrences (all)	0	0	4
HYPOPHAGIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	8 / 70 (11.43%)
occurrences (all)	1	0	12
HYPOVOLAEMIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
LACTIC ACIDOSIS			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 70 (0.00%)
occurrences (all)	0	1	0
MALNUTRITION			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
POLYDIPSIA			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase II: GDC-0032 6 mg QD + Fulvestrant 500 mg	Phase I, Stage 2: Cohort X - GDC-0032 6 mg QD	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	60 / 60 (100.00%)	117 / 122 (95.90%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BENIGN NEOPLASM			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
BRAIN NEOPLASM			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
HAEMANGIOMA OF SKIN			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
LIP NEOPLASM			

subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
PAPILLOMA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
TUMOUR FISTULISATION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
TUMOUR PAIN			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	2 / 60 (3.33%)	5 / 122 (4.10%)	
occurrences (all)	2	6	
DEEP VEIN THROMBOSIS			
subjects affected / exposed	1 / 60 (1.67%)	1 / 122 (0.82%)	
occurrences (all)	1	1	
EMBOLISM VENOUS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
FLUSHING			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
HAEMATOMA			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
HOT FLUSH			
subjects affected / exposed	4 / 60 (6.67%)	1 / 122 (0.82%)	
occurrences (all)	4	1	
HYPOTENSION			
subjects affected / exposed	0 / 60 (0.00%)	6 / 122 (4.92%)	
occurrences (all)	0	7	
JUGULAR VEIN THROMBOSIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	

LYMPHOEDEMA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	12 / 60 (20.00%)	12 / 122 (9.84%)	
occurrences (all)	18	15	
AXILLARY PAIN			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
CATHETER SITE ERYTHEMA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
CATHETER SITE INFLAMMATION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
CATHETER SITE OEDEMA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
CATHETER SITE RASH			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
CHEST DISCOMFORT			
subjects affected / exposed	2 / 60 (3.33%)	0 / 122 (0.00%)	
occurrences (all)	2	0	
CHEST PAIN			
subjects affected / exposed	4 / 60 (6.67%)	2 / 122 (1.64%)	
occurrences (all)	4	2	
CHILLS			
subjects affected / exposed	1 / 60 (1.67%)	6 / 122 (4.92%)	
occurrences (all)	1	7	
DEVICE RELATED THROMBOSIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
EARLY SATIETY			

subjects affected / exposed	0 / 60 (0.00%)	2 / 122 (1.64%)	
occurrences (all)	0	2	
FATIGUE			
subjects affected / exposed	25 / 60 (41.67%)	40 / 122 (32.79%)	
occurrences (all)	39	59	
GAIT DISTURBANCE			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
GENERALISED OEDEMA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	2	
INJECTION SITE ERYTHEMA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
INJECTION SITE PAIN			
subjects affected / exposed	4 / 60 (6.67%)	0 / 122 (0.00%)	
occurrences (all)	4	0	
INJECTION SITE REACTION			
subjects affected / exposed	2 / 60 (3.33%)	0 / 122 (0.00%)	
occurrences (all)	2	0	
MALAISE			
subjects affected / exposed	3 / 60 (5.00%)	2 / 122 (1.64%)	
occurrences (all)	3	2	
MUCOSAL INFLAMMATION			
subjects affected / exposed	17 / 60 (28.33%)	10 / 122 (8.20%)	
occurrences (all)	34	13	
MULTIPLE ORGAN DYSFUNCTION SYNDROME			

subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
OEDEMA			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
OEDEMA PERIPHERAL			
subjects affected / exposed	3 / 60 (5.00%)	14 / 122 (11.48%)	
occurrences (all)	3	21	
PAIN			
subjects affected / exposed	2 / 60 (3.33%)	7 / 122 (5.74%)	
occurrences (all)	2	9	
PERIPHERAL SWELLING			
subjects affected / exposed	1 / 60 (1.67%)	2 / 122 (1.64%)	
occurrences (all)	1	3	
PYREXIA			
subjects affected / exposed	6 / 60 (10.00%)	18 / 122 (14.75%)	
occurrences (all)	7	24	
XEROSIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
CONTRAST MEDIA ALLERGY			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
HYPERSENSITIVITY			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
SEASONAL ALLERGY			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
Reproductive system and breast disorders			

BREAST DISCHARGE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
BREAST MASS			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
BREAST PAIN			
subjects affected / exposed	3 / 60 (5.00%)	0 / 122 (0.00%)	
occurrences (all)	3	0	
DYSPAREUNIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
MENOPAUSAL SYMPTOMS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
PELVIC PAIN			
subjects affected / exposed	0 / 60 (0.00%)	2 / 122 (1.64%)	
occurrences (all)	0	2	
PENILE HAEMORRHAGE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
UTERINE PAIN			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
VAGINAL DISCHARGE			
subjects affected / exposed	1 / 60 (1.67%)	2 / 122 (1.64%)	
occurrences (all)	1	2	
VAGINAL HAEMORRHAGE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
VULVAL DISORDER			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
VULVOVAGINAL BURNING SENSATION			

subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
VULVOVAGINAL DRYNESS			
subjects affected / exposed	5 / 60 (8.33%)	0 / 122 (0.00%)	
occurrences (all)	5	0	
VULVOVAGINAL INFLAMMATION			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
VULVOVAGINAL PRURITUS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
BRONCHOSPASM			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	

COU(

subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
HYPOXIA			
subjects affected / exposed	0 / 60 (0.00%)	2 / 122 (1.64%)	
occurrences (all)	0	2	
INCREASED UPPER AIRWAY SECRETION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
INTERSTITIAL LUNG DISEASE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
LARYNGEAL INFLAMMATION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
LOWER RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
LUNG CONSOLIDATION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
NASAL CONGESTION			
subjects affected / exposed	2 / 60 (3.33%)	2 / 122 (1.64%)	
occurrences (all)	2	2	
NASAL DRYNESS			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
OROPHARYNGEAL DISCOMFORT			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
OROPHARYNGEAL PAIN			
subjects affected / exposed	3 / 60 (5.00%)	4 / 122 (3.28%)	
occurrences (all)	3	4	
PAINFUL RESPIRATION			

subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
PARANASAL SINUS DISCOMFORT			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
PARANASAL SINUS HYPERSECRETION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
PLEURAL EFFUSION			
subjects affected / exposed	1 / 60 (1.67%)	4 / 122 (3.28%)	
occurrences (all)	1	4	
PLEURITIC PAIN			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	2	
PNEUMONIA ASPIRATION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
PNEUMONITIS			
subjects affected / exposed	1 / 60 (1.67%)	6 / 122 (4.92%)	
occurrences (all)	2	7	
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
PULMONARY OEDEMA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
RHINITIS ALLERGIC			
subjects affected / exposed	2 / 60 (3.33%)	1 / 122 (0.82%)	
occurrences (all)	2	1	
RHINORRHOEA			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	2	0	

SINUS CONGESTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
SNEEZING			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
UPPER RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	3 / 60 (5.00%)	0 / 122 (0.00%)	
occurrences (all)	3	0	
WHEEZING			
subjects affected / exposed	2 / 60 (3.33%)	3 / 122 (2.46%)	
occurrences (all)	2	3	
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	4 / 60 (6.67%)	8 / 122 (6.56%)	
occurrences (all)	4	8	
DEPRESSION			
subjects affected / exposed	3 / 60 (5.00%)	4 / 122 (3.28%)	
occurrences (all)	5	4	
AGITATION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
CONFUSIONAL STATE			
subjects affected / exposed	0 / 60 (0.00%)	2 / 122 (1.64%)	
occurrences (all)	0	2	
INSOMNIA			
subjects affected / exposed	9 / 60 (15.00%)	9 / 122 (7.38%)	
occurrences (all)	10	9	
LIBIDO DECREASED			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
MIXED ANXIETY AND DEPRESSIVE DISORDER			

subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
MOOD ALTERED			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
MOOD SWINGS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
Investigations			
WEIGHT DECREASED			
subjects affected / exposed	6 / 60 (10.00%)	24 / 122 (19.67%)	
occurrences (all)	6	36	
ALANINE AMINOTRANSFERASE ABNORMAL			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	4 / 60 (6.67%)	6 / 122 (4.92%)	
occurrences (all)	7	11	
AMYLASE INCREASED			
subjects affected / exposed	3 / 60 (5.00%)	2 / 122 (1.64%)	
occurrences (all)	3	2	
ASPARTATE AMINOTRANSFERASE ABNORMAL			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	5 / 60 (8.33%)	8 / 122 (6.56%)	
occurrences (all)	10	12	
BAND NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	1 / 60 (1.67%)	11 / 122 (9.02%)	
occurrences (all)	2	19	

BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	2 / 60 (3.33%)	3 / 122 (2.46%)	
occurrences (all)	2	13	
BLOOD CALCIUM DECREASED			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	2	
BLOOD CHLORIDE DECREASED			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	1 / 60 (1.67%)	4 / 122 (3.28%)	
occurrences (all)	3	5	
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
BLOOD CREATININE INCREASED			
subjects affected / exposed	2 / 60 (3.33%)	9 / 122 (7.38%)	
occurrences (all)	2	10	
BLOOD INSULIN INCREASED			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
BLOOD MAGNESIUM DECREASED			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
BLOOD MAGNESIUM INCREASED			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
BLOOD PHOSPHORUS INCREASED			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
BLOOD POTASSIUM DECREASED			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
BLOOD TRIGLYCERIDES INCREASED			

subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
BLOOD UREA INCREASED			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
ELECTROCARDIOGRAM QT PROLONGED			
subjects affected / exposed	1 / 60 (1.67%)	1 / 122 (0.82%)	
occurrences (all)	1	1	
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	2 / 60 (3.33%)	6 / 122 (4.92%)	
occurrences (all)	3	7	
HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR INCREASED			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
INVESTIGATION ABNORMAL			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
LIPASE INCREASED			
subjects affected / exposed	1 / 60 (1.67%)	6 / 122 (4.92%)	
occurrences (all)	1	7	
LIVER FUNCTION TEST INCREASED			
subjects affected / exposed	1 / 60 (1.67%)	2 / 122 (1.64%)	
occurrences (all)	1	4	
LOW DENSITY LIPOPROTEIN INCREASED			
subjects affected / exposed	1 / 60 (1.67%)	2 / 122 (1.64%)	
occurrences (all)	1	2	
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
NEUTROPHIL COUNT DECREASED			

subjects affected / exposed	0 / 60 (0.00%)	3 / 122 (2.46%)	
occurrences (all)	0	9	
PLATELET COUNT DECREASED			
subjects affected / exposed	1 / 60 (1.67%)	3 / 122 (2.46%)	
occurrences (all)	1	4	
STREPTOCOCCUS TEST POSITIVE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
TRANSAMINASES INCREASED			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
TROPONIN INCREASED			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
WEIGHT INCREASED			
subjects affected / exposed	2 / 60 (3.33%)	0 / 122 (0.00%)	
occurrences (all)	2	0	
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	1 / 60 (1.67%)	2 / 122 (1.64%)	
occurrences (all)	1	5	
Injury, poisoning and procedural complications			
FALL			
subjects affected / exposed	2 / 60 (3.33%)	3 / 122 (2.46%)	
occurrences (all)	2	3	
ANIMAL BITE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
BURN ORAL CAVITY			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
CHEST INJURY			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
CONTUSION			

subjects affected / exposed	0 / 60 (0.00%)	3 / 122 (2.46%)	
occurrences (all)	0	3	
ESCHAR			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
EYE INJURY			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
HIP FRACTURE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
LIMB FRACTURE			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
LIMB INJURY			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
POST PROCEDURAL HAEMORRHAGE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
PROCEDURAL PAIN			
subjects affected / exposed	2 / 60 (3.33%)	1 / 122 (0.82%)	
occurrences (all)	2	1	
RADIATION SKIN INJURY			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
RIB FRACTURE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
SKIN ABRASION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
SKIN LACERATION			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
SPINAL COMPRESSION FRACTURE			

subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
SUNBURN			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
ULNA FRACTURE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
ANGINA PECTORIS			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
ARRHYTHMIA			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
ATRIAL FIBRILLATION			
subjects affected / exposed	1 / 60 (1.67%)	2 / 122 (1.64%)	
occurrences (all)	1	2	
ATRIOVENTRICULAR BLOCK FIRST DEGREE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
BRADYCARDIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
BUNDLE BRANCH BLOCK LEFT			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
LEFT VENTRICULAR FAILURE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
MITRAL VALVE INCOMPETENCE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
PALPITATIONS			

subjects affected / exposed	3 / 60 (5.00%)	2 / 122 (1.64%)	
occurrences (all)	3	2	
SINUS TACHYCARDIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
TACHYCARDIA			
subjects affected / exposed	0 / 60 (0.00%)	3 / 122 (2.46%)	
occurrences (all)	0	3	
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	7 / 60 (11.67%)	11 / 122 (9.02%)	
occurrences (all)	9	18	
HEADACHE			
subjects affected / exposed	10 / 60 (16.67%)	10 / 122 (8.20%)	
occurrences (all)	11	10	
BALANCE DISORDER			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
CARPAL TUNNEL SYNDROME			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
DISTURBANCE IN ATTENTION			
subjects affected / exposed	0 / 60 (0.00%)	3 / 122 (2.46%)	
occurrences (all)	0	3	
DYSAESTHESIA			
subjects affected / exposed	1 / 60 (1.67%)	2 / 122 (1.64%)	
occurrences (all)	1	2	
DYSARTHRIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
DYSGEUSIA			
subjects affected / exposed	6 / 60 (10.00%)	9 / 122 (7.38%)	
occurrences (all)	6	9	

HYPERSOMNIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
HYPOAESTHESIA			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
LETHARGY			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
MEMORY IMPAIRMENT			
subjects affected / exposed	0 / 60 (0.00%)	2 / 122 (1.64%)	
occurrences (all)	0	2	
MIGRAINE			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
MUSCLE SPASTICITY			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
NEURALGIA			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
NEUROPATHY PERIPHERAL			
subjects affected / exposed	5 / 60 (8.33%)	2 / 122 (1.64%)	
occurrences (all)	5	2	
PARAESTHESIA			
subjects affected / exposed	1 / 60 (1.67%)	3 / 122 (2.46%)	
occurrences (all)	1	3	
PAROSMIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 60 (0.00%)	2 / 122 (1.64%)	
occurrences (all)	0	2	
PRESYNCOPE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	

SCIATICA			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	2	
SEIZURE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
SINUS HEADACHE			

subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
LYMPHOPENIA			
subjects affected / exposed	0 / 60 (0.00%)	10 / 122 (8.20%)	
occurrences (all)	0	18	
NEUTROPENIA			
subjects affected / exposed	1 / 60 (1.67%)	3 / 122 (2.46%)	
occurrences (all)	1	3	
THROMBOCYTOPENIA			
subjects affected / exposed	1 / 60 (1.67%)	8 / 122 (6.56%)	
occurrences (all)	1	14	
Ear and labyrinth disorders			
DEAFNESS UNILATERAL			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
EAR PAIN			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
EXCESSIVE CERUMEN PRODUCTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
HYPOACUSIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
MOTION SICKNESS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
TINNITUS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
VERTIGO			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
Eye disorders			
DIPLOPIA			

subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
DRY EYE			
subjects affected / exposed	4 / 60 (6.67%)	3 / 122 (2.46%)	
occurrences (all)	4	3	
EXOPHTHALMOS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
EYE IRRITATION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
EYE PAIN			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
EYE SWELLING			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
EYELID DISORDER			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
EYELID PTOSIS			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
GLAUCOMA			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
LACRIMATION INCREASED			
subjects affected / exposed	2 / 60 (3.33%)	1 / 122 (0.82%)	
occurrences (all)	2	1	
OCULAR HYPERAEMIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
ORBITAL OEDEMA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
PERIORBITAL OEDEMA			

subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
PERIORBITAL SWELLING			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
PHOTOPHOBIA			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
PHOTOPSIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
SCLERAL HAEMORRHAGE			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
VISION BLURRED			
subjects affected / exposed	2 / 60 (3.33%)	5 / 122 (4.10%)	
occurrences (all)	2	6	
VISUAL IMPAIRMENT			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
VITREOUS FLOATERS			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
DIARRHOEA			
subjects affected / exposed	42 / 60 (70.00%)	77 / 122 (63.11%)	
occurrences (all)	130	158	
ABDOMINAL DISCOMFORT			
subjects affected / exposed	2 / 60 (3.33%)	2 / 122 (1.64%)	
occurrences (all)	2	2	
ABDOMINAL DISTENSION			
subjects affected / exposed	1 / 60 (1.67%)	2 / 122 (1.64%)	
occurrences (all)	1	2	
ABDOMINAL PAIN			
subjects affected / exposed	11 / 60 (18.33%)	18 / 122 (14.75%)	
occurrences (all)	17	30	

ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
ABDOMINAL PAIN UPPER			
subjects affected / exposed	1 / 60 (1.67%)	6 / 122 (4.92%)	
occurrences (all)	1	6	
ABDOMINAL WALL HAEMATOMA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
ANAL HAEMORRHAGE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
ANORECTAL DISCOMFORT			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
APHTHOUS ULCER			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
ASCITES			
subjects affected / exposed	1 / 60 (1.67%)	1 / 122 (0.82%)	
occurrences (all)	1	1	
CHAPPED LIPS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
CHEILITIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
COLITIS			
subjects affected / exposed	9 / 60 (15.00%)	3 / 122 (2.46%)	
occurrences (all)	11	3	
CONSTIPATION			
subjects affected / exposed	6 / 60 (10.00%)	15 / 122 (12.30%)	
occurrences (all)	7	16	
DENTAL CARIES			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	

DIVERTICULUM INTESTINAL			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
DRY MOUTH			
subjects affected / exposed	6 / 60 (10.00%)	8 / 122 (6.56%)	
occurrences (all)	7	8	
DYSPEPSIA			
subjects affected / exposed	14 / 60 (23.33%)	7 / 122 (5.74%)	
occurrences (all)	16	7	
DYSPHAGIA			
subjects affected / exposed	2 / 60 (3.33%)	8 / 122 (6.56%)	
occurrences (all)	2	8	
EPIGASTRIC DISCOMFORT			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
ERUCTATION			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
FAECES DISCOLOURED			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
FLATULENCE			
subjects affected / exposed	1 / 60 (1.67%)	4 / 122 (3.28%)	
occurrences (all)	1	4	
FREQUENT BOWEL MOVEMENTS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
GASTRIC ULCER			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
GASTRITIS			
subjects affected / exposed	1 / 60 (1.67%)	1 / 122 (0.82%)	
occurrences (all)	1	1	
GASTROOESOPHAGEAL REFLUX DISEASE			

subjects affected / exposed	6 / 60 (10.00%)	7 / 122 (5.74%)	
occurrences (all)	6	7	
GINGIVAL PAIN			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
GLOSSITIS			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
GLOSSODYNIA			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
HAEMATOCHEZIA			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
HAEMORRHOIDS			
subjects affected / exposed	1 / 60 (1.67%)	2 / 122 (1.64%)	
occurrences (all)	1	2	
HYPERCHLORHYDRIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
HYPOAESTHESIA ORAL			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
LARGE INTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
LIP PAIN			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
MESENTERIC ARTERY THROMBOSIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
MOUTH ULCERATION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
NAUSEA			

subjects affected / exposed	27 / 60 (45.00%)	55 / 122 (45.08%)	
occurrences (all)	39	77	
ODYNOPHAGIA			
subjects affected / exposed	0 / 60 (0.00%)	2 / 122 (1.64%)	
occurrences (all)	0	2	
OESOPHAGEAL PAIN			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
OESOPHAGITIS			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	2	
ORAL DYSAESTHESIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
ORAL PAIN			
subjects affected / exposed	1 / 60 (1.67%)	5 / 122 (4.10%)	
occurrences (all)	1	6	
PARAESTHESIA ORAL			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
PERIODONTAL DISEASE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
PROCTALGIA			
subjects affected / exposed	0 / 60 (0.00%)	4 / 122 (3.28%)	
occurrences (all)	0	5	
PROCTITIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
RECTAL TENESMUS			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
RETCHING			

subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
STOMATITIS			
subjects affected / exposed	11 / 60 (18.33%)	26 / 122 (21.31%)	
occurrences (all)	21	40	
TOOTHACHE			
subjects affected / exposed	2 / 60 (3.33%)	3 / 122 (2.46%)	
occurrences (all)	2	3	
VARICOSE VEINS SUBLINGUAL			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
VOMITING			
subjects affected / exposed	6 / 60 (10.00%)	30 / 122 (24.59%)	
occurrences (all)	9	42	
Hepatobiliary disorders			
HEPATIC PAIN			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
RASH			
subjects affected / exposed	15 / 60 (25.00%)	19 / 122 (15.57%)	
occurrences (all)	22	29	
ALOPECIA			
subjects affected / exposed	7 / 60 (11.67%)	3 / 122 (2.46%)	
occurrences (all)	8	3	
BLISTER			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
COLD SWEAT			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
DECUBITUS ULCER			

subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
DERMATITIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
DERMATITIS ACNEIFORM			
subjects affected / exposed	1 / 60 (1.67%)	2 / 122 (1.64%)	
occurrences (all)	1	3	
DERMATITIS ALLERGIC			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
DERMATITIS EXFOLIATIVE GENERALISED			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
DRY SKIN			
subjects affected / exposed	16 / 60 (26.67%)	9 / 122 (7.38%)	
occurrences (all)	18	11	
DYSHIDROTIC ECZEMA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
ECCHYMOSIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
ECZEMA			
subjects affected / exposed	1 / 60 (1.67%)	2 / 122 (1.64%)	
occurrences (all)	1	5	
ECZEMA ASTEATOTIC			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
ERYTHEMA			
subjects affected / exposed	1 / 60 (1.67%)	2 / 122 (1.64%)	
occurrences (all)	1	2	
EXFOLIATIVE RASH			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	

HYPERHIDROSIS			
subjects affected / exposed	1 / 60 (1.67%)	2 / 122 (1.64%)	
occurrences (all)	1	2	
INGROWING NAIL			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
NAIL DISCOLOURATION			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
NAIL DISORDER			
subjects affected / exposed	1 / 60 (1.67%)	2 / 122 (1.64%)	
occurrences (all)	1	2	
NAIL DYSTROPHY			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
NIGHT SWEATS			
subjects affected / exposed	0 / 60 (0.00%)	2 / 122 (1.64%)	
occurrences (all)	0	2	
ONYCHOCLASIS			
subjects affected / exposed	2 / 60 (3.33%)	0 / 122 (0.00%)	
occurrences (all)	2	0	
ONYCHOLYSIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
ONYCHOMADESIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
PAIN OF SKIN			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
PAPULE			

subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
PHOTOSENSITIVITY REACTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
PRURITUS			
subjects affected / exposed	5 / 60 (8.33%)	16 / 122 (13.11%)	
occurrences (all)	10	23	
PRURITUS ALLERGIC			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
PSORIASIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
RASH MACULAR			
subjects affected / exposed	0 / 60 (0.00%)	2 / 122 (1.64%)	
occurrences (all)	0	2	
RASH MACULO-PAPULAR			
subjects affected / exposed	5 / 60 (8.33%)	18 / 122 (14.75%)	
occurrences (all)	9	26	
RASH PAPULAR			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
RASH VESICULAR			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
ROSACEA			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
SEBORRHOEIC DERMATITIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
SKIN EXFOLIATION			

subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	2	
SKIN FISSURES			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
SKIN HYPERPIGMENTATION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
SKIN PLAQUE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
SKIN TIGHTNESS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
SKIN ULCER			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
URTICARIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	1 / 60 (1.67%)	4 / 122 (3.28%)	
occurrences (all)	1	4	
AZOTAEMIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
BLADDER DISCOMFORT			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
BLADDER SPASM			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
CHROMATURIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	

CYSTITIS NONINFECTIVE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
DYSURIA			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
HAEMATURIA			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
HYDRONEPHROSIS			
subjects affected / exposed	0 / 60 (0.00%)	2 / 122 (1.64%)	
occurrences (all)	0	2	
MICTURITION URGENCY			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
POLLAKIURIA			
subjects affected / exposed	2 / 60 (3.33%)	3 / 122 (2.46%)	
occurrences (all)	2	3	
POLYURIA			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
PROTEINURIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
RENAL FAILURE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
URETERIC OBSTRUCTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
URETERIC STENOSIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
URINARY HESITATION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	

URINARY RETENTION			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	2	
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 60 (0.00%)	2 / 122 (1.64%)	
occurrences (all)	0	2	
URINARY TRACT PAIN			
subjects affected / exposed	0 / 60 (0.00%)	2 / 122 (1.64%)	
occurrences (all)	0	2	
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	8 / 60 (13.33%)	11 / 122 (9.02%)	
occurrences (all)	11	14	
ARTHRALGIA			
subjects affected / exposed	14 / 60 (23.33%)	7 / 122 (5.74%)	
occurrences (all)	16	9	
ARTHRITIS			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
BONE PAIN			
subjects affected / exposed	4 / 60 (6.67%)	1 / 122 (0.82%)	
occurrences (all)	4	1	
FLANK PAIN			
subjects affected / exposed	0 / 60 (0.00%)	3 / 122 (2.46%)	
occurrences (all)	0	6	
GROIN PAIN			
subjects affected / exposed	0 / 60 (0.00%)	2 / 122 (1.64%)	
occurrences (all)	0	2	
INTERVERTEBRAL DISC PROTRUSION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
JOINT RANGE OF MOTION DECREASED			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
JOINT SWELLING			

subjects affected / exposed	0 / 60 (0.00%)	3 / 122 (2.46%)	
occurrences (all)	0	4	
MUSCLE DISORDER			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
MUSCLE SPASMS			
subjects affected / exposed	7 / 60 (11.67%)	9 / 122 (7.38%)	
occurrences (all)	8	11	
MUSCLE TIGHTNESS			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 60 (0.00%)	3 / 122 (2.46%)	
occurrences (all)	0	3	
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	2 / 60 (3.33%)	4 / 122 (3.28%)	
occurrences (all)	2	4	
MUSCULOSKELETAL DISCOMFORT			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
MUSCULOSKELETAL STIFFNESS			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
MYALGIA			
subjects affected / exposed	2 / 60 (3.33%)	7 / 122 (5.74%)	
occurrences (all)	2	7	
NECK PAIN			
subjects affected / exposed	5 / 60 (8.33%)	2 / 122 (1.64%)	
occurrences (all)	5	2	
OSTEONECROSIS OF JAW			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
PAIN IN EXTREMITY			

subjects affected / exposed	4 / 60 (6.67%)	2 / 122 (1.64%)	
occurrences (all)	5	2	
PAIN IN JAW			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
SPINAL PAIN			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
NASOPHARYNGITIS			
subjects affected / exposed	3 / 60 (5.00%)	2 / 122 (1.64%)	
occurrences (all)	3	2	
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	4 / 60 (6.67%)	6 / 122 (4.92%)	
occurrences (all)	4	13	
URINARY TRACT INFECTION			
subjects affected / exposed	8 / 60 (13.33%)	16 / 122 (13.11%)	
occurrences (all)	8	18	
BACTERAEMIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
CANDIDA INFECTION			
subjects affected / exposed	1 / 60 (1.67%)	3 / 122 (2.46%)	
occurrences (all)	1	3	
CATHETER SITE INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
CELLULITIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
CLOSTRIDIUM DIFFICILE INFECTION			

subjects affected / exposed	2 / 60 (3.33%)	2 / 122 (1.64%)	
occurrences (all)	2	2	
CONJUNCTIVITIS			
subjects affected / exposed	0 / 60 (0.00%)	3 / 122 (2.46%)	
occurrences (all)	0	3	
CONJUNCTIVITIS VIRAL			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
CYSTITIS			
subjects affected / exposed	1 / 60 (1.67%)	1 / 122 (0.82%)	
occurrences (all)	1	1	
CYTOMEGALOVIRUS INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
DIENTAMOEBA INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
EAR INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
ERYTHEMA INDURATUM			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
FUNGAL INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
FUNGAL SKIN INFECTION			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
FURUNCLE			
subjects affected / exposed	1 / 60 (1.67%)	0 / 122 (0.00%)	
occurrences (all)	1	0	
GASTROINTESTINAL VIRAL			

INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
GINGIVITIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
GROIN ABSCESS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
HERPES ZOSTER			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
HORDEOLUM			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
LARYNGITIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
LOCALISED INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	2	
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
MASTITIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
MUCOSAL INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
NAIL INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
ORAL CANDIDIASIS			

subjects affected / exposed	0 / 60 (0.00%)	2 / 122 (1.64%)	
occurrences (all)	0	2	
ORAL HERPES			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
PARONYCHIA			
subjects affected / exposed	0 / 60 (0.00%)	2 / 122 (1.64%)	
occurrences (all)	0	2	
PHARYNGITIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
PNEUMONIA			
subjects affected / exposed	1 / 60 (1.67%)	2 / 122 (1.64%)	
occurrences (all)	1	2	
PURULENT DISCHARGE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
PYELONEPHRITIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
RESPIRATORY SYNCYTIAL VIRUS INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 60 (1.67%)	1 / 122 (0.82%)	
occurrences (all)	1	1	
SINUSITIS			
subjects affected / exposed	3 / 60 (5.00%)	1 / 122 (0.82%)	
occurrences (all)	3	1	
SKIN CANDIDA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
SKIN INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	

STOMA SITE INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
TOOTH ABSCESS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
TOOTH INFECTION			
subjects affected / exposed	1 / 60 (1.67%)	1 / 122 (0.82%)	
occurrences (all)	1	1	
URINARY TRACT INFECTION BACTERIAL			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
VAGINAL INFECTION			
subjects affected / exposed	1 / 60 (1.67%)	1 / 122 (0.82%)	
occurrences (all)	1	1	
VARICELLA ZOSTER VIRUS INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
VIRAL INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
VULVOVAGINAL MYCOTIC INFECTION			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	19 / 60 (31.67%)	38 / 122 (31.15%)	
occurrences (all)	30	53	
DEHYDRATION			
subjects affected / exposed	0 / 60 (0.00%)	14 / 122 (11.48%)	
occurrences (all)	0	23	

ELECTROLYTE IMBALANCE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
FAILURE TO THRIVE			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
FLUID OVERLOAD			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
GLUCOSE TOLERANCE IMPAIRED			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
HYPERCALCAEMIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
HYPERCHOLESTEROLAEMIA			
subjects affected / exposed	4 / 60 (6.67%)	2 / 122 (1.64%)	
occurrences (all)	5	3	
HYPERGLYCAEMIA			
subjects affected / exposed	13 / 60 (21.67%)	43 / 122 (35.25%)	
occurrences (all)	24	96	
HYPERKALAEMIA			
subjects affected / exposed	0 / 60 (0.00%)	2 / 122 (1.64%)	
occurrences (all)	0	2	
HYPERMAGNESAEMIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
HYPERPHOSPHATAEMIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
HYPERTRIGLYCERIDAEMIA			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
HYPERURICAEMIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	

HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 60 (0.00%)	4 / 122 (3.28%)	
occurrences (all)	0	7	
HYPOCALCAEMIA			
subjects affected / exposed	2 / 60 (3.33%)	3 / 122 (2.46%)	
occurrences (all)	3	3	
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
HYPOKALAEMIA			
subjects affected / exposed	6 / 60 (10.00%)	23 / 122 (18.85%)	
occurrences (all)	6	40	
HYPOMAGNESAEMIA			
subjects affected / exposed	2 / 60 (3.33%)	12 / 122 (9.84%)	
occurrences (all)	2	21	
HYPONATRAEMIA			
subjects affected / exposed	1 / 60 (1.67%)	12 / 122 (9.84%)	
occurrences (all)	1	22	
HYPOPHAGIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
HYPOPHOSPHATAEMIA			
subjects affected / exposed	1 / 60 (1.67%)	7 / 122 (5.74%)	
occurrences (all)	1	16	
HYPOVOLAEMIA			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
LACTIC ACIDOSIS			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	
MALNUTRITION			
subjects affected / exposed	0 / 60 (0.00%)	1 / 122 (0.82%)	
occurrences (all)	0	1	
POLYDIPSIA			
subjects affected / exposed	0 / 60 (0.00%)	0 / 122 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 August 2011	Changes in Protocol v2 were as follows: DLT definition for Grade ≥3 hyperglycemia was revised to include use of anti-hyperglycemic medication for adequate time period to manage hyperglycemia. Guidelines for hyperglycemia management were updated. Inclusion criterion regarding subjects with prostate cancer was revised to include a requirement that subjects must be castrate-resistant. Inclusion criterion for subjects with ovarian cancer based on CA-125 levels was revised to be consistent with Gynecologic Cancer Intergroup (GCIG) Criteria for Evaluation According to CA-125. Appendix E was revised to reflect these criteria. Requirement for subjects to receive standard low-fat meal at 4 hr postdose was removed. Use of proton-pump inhibitors, H2-histamine receptor antagonists, antacids were excluded only for subjects in Stage 2. Language regarding use of hematopoietic colony-stimulating factors was revised to add that these agents should not be initiated or increased in dose from 7 days before Cycle 1 Day 1 until completion of the DLT Assess 1 Day

07 March 2013	Changes in Protocol v5 were as follows: A Phase II portion was added. This consisted of an open-label, single-arm study that will enroll a total of 60 subjects with HER2-negative, hormone receptor-positive breast cancer to be treated with GDC-0032 and fulvestrant. Dose of GDC-0032 in combination with fulvestrant was based upon clinical data obtained in Stage 1 and Stage 2. Statistical justification for the sizing of this study was included. Cohorts A and B in Stage 2 were increased in size to 20 subjects. Rationale and statistical justification for this change was added. Cohort G in Stage 2 was added and consisted of 20 subjects with solid tumors that had increased PIK3CA copy number. Rationale and statistical justification for this cohort was added. The subject numbers for Stage 2, Cohorts E and F were clarified. Approximately 20−26 subjects were enrolled in Cohorts E and F since subjects had been treated at 2 dose levels. Six subjects were tested at 9 mg dose level prior to the decision to expand to a total of 20 subjects at 6 mg. Language clarifying this was added. Dose modification guidelines were updated to provide clearer guidance to investigators. Several adverse events of special interest were added. Clinical data were updated and includes safety and efficacy data. Updates to the dose selected for Stage 2 cohorts were included.Inclusion criteria regarding hemoglobin and liver function tests in the setting of liver metastases were updated to reflect the subjects population that would be appropriate candidates for this trial. Exclusion criteria regarding subjects with brain metastases and language regarding GDC-0032 treatment after treatment of brain metastases were updated to better reflect the subject population eligible for this study and the risk-benefit profile for treatment with GDC-0032.
24 June 2013	Changes in Protocol v6 were as follows: Clinical safety data were updated. Toxicities observed with GDC-0032 in clinical studies were updated. This included updated data on colitis observed in GDC-0032 trials. Management guidelines for toxicities including hyperglycemia, pneumonitis, rash, diarrhea, colitis, stomatitis, and other clinically significant adverse events were updated. Eligibility criteria were updated to exclude subjects with active small or large intestine inflammation such as Crohn's disease or ulcerative colitis. Protocol-defined events of special interest were updated to include Grade ≥ 2 colitis or enterocolitis and Grade ≥ 3 diarrhea.
16 December 2013	Changes in Protocol v7 were as follows: Additional cohorts (Cohorts J, K and L) were added to investigate different dosing schedules of GDC-0032 in combination with fulvestrant. Preliminary efficacy in Cohort F had demonstrated that some subjects who started at GDC-0032 6-mg QD dose and then dose reduced to 3 mg QD still maintained a partial response. Several alternate dose schedules were tested to obtain further data on relative tolerability of adding intermittent breaks to GDC-0032 dosing schedule. Preliminary efficacy was observed in expansion cohort of solid non-breast tumors with PIK3CA mutation (Cohort B). Cohort H was added and will test GDC-0032 QD on a 21-day on, 7-day off schedule in approximately 40 subjects with non-breast, non-colorectal solid tumors. Management guidelines for diarrhea were updated to reflect the increased clinical experience of GDC-0032. For non-infectious diarrhea, corticosteroid treatment was useful in alleviating symptoms. Dose modification guidelines for diarrhea and colitis were updated as prompt management of Grade 2 diarrhea may prevent worsened subsequent gastrointestinal toxicities. Language was added to provide investigators the option to treat subjects with asymptomatic increases in lipase and amylase lab values. Inclusion criteria regarding Phase II population was clarified. Phase II subjects must be postmenopausal, HER2-negative, and hormone receptor-positive breast cancer subjects. Exclusion criteria was modified to reflect clinical practice regarding the minimal washout time for oral endocrine agents taken daily. Washout was decreased from 3 weeks to 2 weeks (e.g., letrozole, anastrozole, exemestane, tamoxifen). Exclusion criteria regarding hypokalemia and hypomagnesemia was removed to reflect clinical practice while maintaining subject safety based upon updated GDC-0032 clinical data. Enrollment numbers for Stage 2, Cohorts C−F have been updated to reflect actual enrollment into study. Clinical safety data was updated.

12 May 2014	Changes in Protocol v8 were as follows: GDC-0032 tablet formulation information was added to allow the use of tablets in this study. Information regarding the relative bioavailability of GDC-0032 capsules and tablets was included. The dose modification table (Table 8) was updated to reflect usage of tablets. Cohorts M, N and P were added to investigate daily dosing of 2 mg GDC-0032 tablets in combination with fulvestrant or letrozole and 4 mg GDC-0032 in tablet form dosed daily with letrozole. The requirement for taking GDC-0032 on an empty stomach was removed. To allow subjects currently being treated with GDC-0032 via capsules to continue obtaining GDC-0032 treatment, subjects may be switched over from capsules to tablets. Management guidelines for adverse events of special interest were updated. More detailed information on the dosage of recommended corticosteroids for diarrhea and colitis was included. In addition, extra language regarding caution with using steroids was added.
31 March 2015	Changes in Protocol v9 were as follows: The title of the study was revised to add subjects with non-Hodgkin's lymphoma. The formulation of the study drug, GDC-0032 (capsule or tablet), was added to each reference of the drug for clarity.
29 September 2016	Changes in Protocol v10 were as follows: Cohorts Q, R, and S, which will enroll postmenopausal subjects with locally advanced or metastatic HER2-negative, hormone receptor−positive breast cancer that had progressed or failed to respond to at least one prior endocrine therapy in the adjuvant or metastatic setting, were added to evaluate alternative dosing schedules of GDC 0032 in combination with letrozole. Cohort T enrolled subjects with non-Hodgkin's lymphoma whose cancers have progressed or failed to respond to at least one prior regimen and who are not candidates for regimens known to provide clinical benefit. Cohort X enrolled subjects with PIK3CA-mutant solid tumors whose cancers had progressed or failed to respond to at least one prior regimen and who are not candidates for regimens known to provide clinical benefit. The PK measurements for Cohorts L and S were modified. In sub-Cohort X3, more-dense PK measurements were made for subjects with head and neck cancer taking GDC-0032 in suspension form. Cohort T had additional specific assessments based on the International Working Group Revised Response Criteria for Malignant Lymphoma, including assessment of B-symptoms and bone marrow aspiration and biopsy. Six additional subject slots (3 subjects with PIK3CA wild-type and 3 subjects with PIK3CA-mutant tumors) were added to each of the letrozole combination Cohorts N and P. Specific alkaline phosphatase levels were removed as inclusion criteria. Additional inclusion and exclusion criteria were added to allow for subjects with additional cancers such as head and neck squamous-cell carcinomas (HNSCC) and non-Hodgkin's lymphomas. Management guidelines for GDC-0032-related toxicities were updated. Tables, figures, and appendices were modified to reflect changes to the protocol.
12 July 2018	Changes in Protocol v11 were as follows: The following sections were updated to reflect these changes: Section 3.1 (Description of the Study), Section 4.5 (Study Assessments), Section 4.5.3 (Assessments during Treatment), Appendix A-7 (Study Flowchart: Stage 2, Cohorts H, J, K, L, M, N, P, Q, R, S, T, T2, and X [X1-X11] before LPI - 6 Months). The new adverse drug reactions were added to Section 3.4.3, and management guidelines for infection were added to Section 3.4.5.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
31 May 2021	The Sponsor discontinued the manufacturing and development of taselisib due to modest clinical benefit and limited tolerability.	-

Notes:

Limitations and caveats

None reported