Clinical trial results:
Open-Label, Phase 2 Study to Evaluate the Safety and Efficacy of the Combination of ABT-450/Ritonavir/ABT-267 With ABT-333 and With or Without RBV in HCV Genotype 1 and ABT-450/r/ABT-267 With RBV in HCV GT4-Infected Adult Liver or Renal Transplant Recipients With Hepatitis C Virus (HCV) Infection (CORAL-I)

Summary

EudraCT number	2012-004792-39
Trial protocol	ES GB DE
Global end of trial date	13 July 2017

Results information

Result version number	v1 (current)
This version publication date	25 November 2017
First version publication date	25 November 2017

Trial information

Trial identification

Sponsor protocol code	M12-999

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01782495
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	AbbVie Deutschland GmbH & Co. KG
Sponsor organisation address	AbbVie House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire, United Kingdom, SL6-4UB
Public contact	Global Medical Services, AbbVie, 001 800-633-9110,
Scientific contact	Emily Dumas, AbbVie, emily.dumas@abbvie.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	13 July 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	13 July 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to evaluate the safety and efficacy of ABT-450/r/ABT-267 with or without ABT-333 and with or without ribavirin (RBV) in adult liver or renal transplant recipients with hepatitis C virus (HCV) genotype 1 or 4 (GT1 or GT4) infection.

Protection of trial subjects:

Subject read and understood the information provided about the study and gave written permission.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 February 2013
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	Australia: 8
Country: Number of subjects enrolled	France: 2
Country: Number of subjects enrolled	Germany: 3
Country: Number of subjects enrolled	United Kingdom: 14
Country: Number of subjects enrolled	Spain: 16
Country: Number of subjects enrolled	United States: 86
Worldwide total number of subjects	129
EEA total number of subjects	35

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)	97
From 65 to 84 years	32
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

This study included a 35-day screening period.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm A

Arm description:

Liver transplant recipients with HCV genotype 1 infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 24 weeks.

Arm type	Experimental
Investigational medicinal product name	ombitasvir/paritaprevir/ritonavir
Investigational medicinal product code	
Other name	Viekirax, ombitasvir also known as ABT-267, paritaprevir also known as ABT-450
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

ombitasvir (25 mg) coformulated with paritaprevir (150 mg) and ritonavir (100 mg) twice daily

Investigational medicinal product name	dasabuvir
Investigational medicinal product code	
Other name	Exviera, ABT-333
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

dasabuvir 250 mg twice daily

Investigational medicinal product name	ribavirin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Weight-based (dosed 1,000 or 1,200 mg daily divided twice a day)

Arm title	Arm B

Arm description:

Liver transplant recipients with HCV genotype 1a or genotype 1b (dependent on prior treatment experience and response) infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 24 weeks.

Arm type	Experimental

Investigational medicinal product name	ombitasvir/paritaprevir/ritonavir
Investigational medicinal product code	
Other name	Viekirax, ombitasvir also known as ABT-267, paritaprevir also known as ABT-450
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

ombitasvir (25 mg) coformulated with paritaprevir (150 mg) and ritonavir (100 mg) twice daily

Investigational medicinal product name	dasabuvir
Investigational medicinal product code	
Other name	Exviera, ABT-333
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

dasabuvir 250 mg twice daily

Investigational medicinal product name	ribavirin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Weight-based (dosed 1,000 or 1,200 mg daily divided twice a day)

Arm title	Arm C

Arm description:

Liver transplant receipts with HCV genotype 1b infection who were treatment naïve or prior responders to interferon treatment without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) for 24 weeks.

Arm type	Experimental
Investigational medicinal product name	ombitasvir/paritaprevir/ritonavir
Investigational medicinal product code	
Other name	Viekirax, ombitasvir also known as ABT-267, paritaprevir also known as ABT-450
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

ombitasvir (25 mg) coformulated with paritaprevir (150 mg) and ritonavir (100 mg) twice daily

Investigational medicinal product name	dasabuvir
Investigational medicinal product code	
Other name	Exviera, ABT-333
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

dasabuvir 250 mg twice daily

Arm title	Arm D

Arm description:

Liver transplant recipients with HCV genotype 1a infection with Child Pugh A cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) plus weight-based ribavirin (dosed 1,000 or 1,200 mg daily divided twice a day) for 24 weeks.

Arm type	Experimental

Investigational medicinal product name	ombitasvir/paritaprevir/ritonavir
Investigational medicinal product code	
Other name	Viekirax, ombitasvir also known as ABT-267, paritaprevir also known as ABT-450
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

ombitasvir (25 mg) coformulated with paritaprevir (150 mg) and ritonavir (100 mg) twice daily

Investigational medicinal product name	dasabuvir
Investigational medicinal product code	
Other name	Exviera, ABT-333
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

dasabuvir 250 mg twice daily

Investigational medicinal product name	ribavirin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Weight-based (dosed 1,000 or 1,200 mg daily divided twice a day)

Arm title	Arm E

Arm description:

Liver transplant recipients with HCV genotype 1b infection with Child Pugh A cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 12 weeks.

Arm type	Experimental
Investigational medicinal product name	ombitasvir/paritaprevir/ritonavir
Investigational medicinal product code	
Other name	Viekirax, ombitasvir also known as ABT-267, paritaprevir also known as ABT-450
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

ombitasvir (25 mg) coformulated with paritaprevir (150 mg) and ritonavir (100 mg) twice daily

Investigational medicinal product name	dasabuvir
Investigational medicinal product code	
Other name	Exviera, ABT-333
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

dasabuvir 250 mg twice daily

Investigational medicinal product name	ribavirin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Weight-based (dosed 1,000 or 1,200 mg daily divided twice a day)

Arm title	Arm F

Arm description:

Liver transplant recipients with HCV genotype 1a infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 12 weeks.

Arm type	Experimental
Investigational medicinal product name	ombitasvir/paritaprevir/ritonavir
Investigational medicinal product code	
Other name	Viekirax, ombitasvir also known as ABT-267, paritaprevir also known as ABT-450
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

ombitasvir (25 mg) coformulated with paritaprevir (150 mg) and ritonavir (100 mg) twice daily

Investigational medicinal product name	dasabuvir
Investigational medicinal product code	
Other name	Exviera, ABT-333
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

dasabuvir 250 mg twice daily

Investigational medicinal product name	ribavirin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Weight-based (dosed 1,000 or 1,200 mg daily divided twice a day)

Arm title	Arm G

Arm description:

Liver transplant recipients with HCV genotype 1b infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) for 12 weeks.

Arm type	Experimental
Investigational medicinal product name	ombitasvir/paritaprevir/ritonavir
Investigational medicinal product code	
Other name	Viekirax, ombitasvir also known as ABT-267, paritaprevir also known as ABT-450
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

ombitasvir (25 mg) coformulated with paritaprevir (150 mg) and ritonavir (100 mg) twice daily

Investigational medicinal product name	dasabuvir
Investigational medicinal product code	
Other name	Exviera, ABT-333
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

dasabuvir 250 mg twice daily

Arm title	Arm H

Arm description:

Renal transplant recipients with HCV genotype 1a infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 12 weeks.

Arm type	Experimental
Investigational medicinal product name	ombitasvir/paritaprevir/ritonavir
Investigational medicinal product code	
Other name	Viekirax, ombitasvir also known as ABT-267, paritaprevir also known as ABT-450
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

ombitasvir (25 mg) coformulated with paritaprevir (150 mg) and ritonavir (100 mg) twice daily

Investigational medicinal product name	dasabuvir
Investigational medicinal product code	
Other name	Exviera, ABT-333
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

dasabuvir 250 mg twice daily

Investigational medicinal product name	ribavirin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Weight-based (dosed 1,000 or 1,200 mg daily divided twice a day)

Arm title	Arm I

Arm description:

Renal transplant recipients with HCV genotype 1b infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) for 12 weeks.

Arm type	Experimental
Investigational medicinal product name	ombitasvir/paritaprevir/ritonavir
Investigational medicinal product code	
Other name	Viekirax, ombitasvir also known as ABT-267, paritaprevir also known as ABT-450
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

ombitasvir (25 mg) coformulated with paritaprevir (150 mg) and ritonavir (100 mg) twice daily

Investigational medicinal product name	dasabuvir
Investigational medicinal product code	
Other name	Exviera, ABT-333
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

dasabuvir 250 mg twice daily

Arm title	Arm J

Arm description:

Liver transplant recipients with HCV genotype 4 infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 12 weeks.

Arm type	Experimental

Investigational medicinal product name	ombitasvir/paritaprevir/ritonavir
Investigational medicinal product code	
Other name	Viekirax, ombitasvir also known as ABT-267, paritaprevir also known as ABT-450
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

ombitasvir (25 mg) coformulated with paritaprevir (150 mg) and ritonavir (100 mg) twice daily

Investigational medicinal product name	ribavirin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Weight-based (dosed 1,000 or 1,200 mg daily divided twice a day)

Arm title	Arm K

Arm description:

Liver transplant recipients with HCV genotype 4 infection with Child Pugh A cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 24 weeks.

Arm type	Experimental
Investigational medicinal product name	ombitasvir/paritaprevir/ritonavir
Investigational medicinal product code	
Other name	Viekirax, ombitasvir also known as ABT-267, paritaprevir also known as ABT-450
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

ombitasvir (25 mg) coformulated with paritaprevir (150 mg) and ritonavir (100 mg) twice daily

Investigational medicinal product name	ribavirin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Weight-based (dosed 1,000 or 1,200 mg daily divided twice a day)

Number of subjects in period 1	Arm A	Arm B	Arm C
Started	34	27	13
Completed	34	26	13
Not completed	0	1	0
Adverse event	-	-	-
Withdrew consent	-	1	-

Number of subjects in period 1	Arm D	Arm E	Arm F
Started	4	2	22
Completed	4	2	22
Not completed	0	0	0

Adverse event	-	-	-
Withdrew consent	-	-	-

Number of subjects in period 1	Arm G	Arm H	Arm I
Started	12	9	3
Completed	12	6	3
Not completed	0	3	0
Adverse event	-	2	-
Withdrew consent	-	1	-

Number of subjects in period 1	Arm J	Arm K
Started	2	1
Completed	2	1
Not completed	0	0
Adverse event	-	-
Withdrew consent	-	-

Baseline characteristics

Reporting groups

Reporting group title	Arm A

Reporting group description:

Liver transplant recipients with HCV genotype 1 infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 24 weeks.

Reporting group title	Arm B

Reporting group description:

Liver transplant recipients with HCV genotype 1a or genotype 1b (dependent on prior treatment experience and response) infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 24 weeks.

Reporting group title	Arm C

Reporting group description:

Liver transplant receipts with HCV genotype 1b infection who were treatment naïve or prior responders to interferon treatment without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) for 24 weeks.

Reporting group title	Arm D

Reporting group description:

Liver transplant recipients with HCV genotype 1a infection with Child Pugh A cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) plus weight-based ribavirin (dosed 1,000 or 1,200 mg daily divided twice a day) for 24 weeks.

Reporting group title	Arm E

Reporting group description:

Liver transplant recipients with HCV genotype 1b infection with Child Pugh A cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 12 weeks.

Reporting group title	Arm F

Reporting group description:

Liver transplant recipients with HCV genotype 1a infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 12 weeks.

Reporting group title	Arm G

Reporting group description:

Liver transplant recipients with HCV genotype 1b infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) for 12 weeks.

Reporting group title	Arm H

Reporting group description:

Renal transplant recipients with HCV genotype 1a infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 12 weeks.

Reporting group title	Arm I

Reporting group description:

Renal transplant recipients with HCV genotype 1b infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) for 12 weeks.

Reporting group title	Arm J

Reporting group description:

Liver transplant recipients with HCV genotype 4 infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 12 weeks.

Reporting group title	Arm K

Reporting group description:

Liver transplant recipients with HCV genotype 4 infection with Child Pugh A cirrhosis received

ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 24 weeks.

Reporting group values	Arm A	Arm B	Arm C
Number of subjects	34	27	13
Age categorical			
Units: Subjects			

Age continuous			
Intent-to-treat (ITT) population: All participants who received at least 1 dose of study drug. 77777=The estimated standard deviation of one sample is undefined			
Units: years			
arithmetic mean	59.6	58	61.8
standard deviation	± 6.62	± 6.66	± 5.76
Gender categorical			
Intent-to-treat (ITT) population: All participants who received at least 1 dose of study drug.			
Units: Subjects			
Female	7	4	5
Male	27	23	8

Reporting group values	Arm D	Arm E	Arm F
Number of subjects	4	2	22
Age categorical			
Units: Subjects			

Age continuous			
Intent-to-treat (ITT) population: All participants who received at least 1 dose of study drug. 77777=The estimated standard deviation of one sample is undefined			
Units: years			
arithmetic mean	59.8	78	58.3
standard deviation	± 10.78	± 1.41	± 9.35
Gender categorical			
Intent-to-treat (ITT) population: All participants who received at least 1 dose of study drug.			
Units: Subjects			
Female	0	2	2
Male	4	0	20

Reporting group values	Arm G	Arm H	Arm I
Number of subjects	12	9	3
Age categorical			
Units: Subjects			

Age continuous			
Intent-to-treat (ITT) population: All participants who received at least 1 dose of study drug. 77777=The estimated standard deviation of one sample is undefined			
Units: years			
arithmetic mean	62.2	58	57.3
standard deviation	± 7.64	± 8	± 9.29

Gender categorical			
Intent-to-treat (ITT) population: All participants who received at least 1 dose of study drug.			
Units: Subjects			
Female	2	2	1
Male	10	7	2

Reporting group values	Arm J	Arm K	Total
Number of subjects	2	1	129
Age categorical Units: Subjects			

Age continuous			
Intent-to-treat (ITT) population: All participants who received at least 1 dose of study drug. 77777=The estimated standard deviation of one sample is undefined			
Units: years			
arithmetic mean	63.5	50	
standard deviation	± 7.78	± 77777	-
Gender categorical			
Intent-to-treat (ITT) population: All participants who received at least 1 dose of study drug.			
Units: Subjects			
Female	0	0	25
Male	2	1	104

End points

End points reporting groups

Reporting group title	Arm A
Reporting group description:	
Liver transplant recipients with HCV genotype 1 infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 24 weeks.	
Reporting group title	Arm B
Reporting group description:	
Liver transplant recipients with HCV genotype 1a or genotype 1b (dependent on prior treatment experience and response) infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 24 weeks.	
Reporting group title	Arm C
Reporting group description:	
Liver transplant receipts with HCV genotype 1b infection who were treatment naïve or prior responders to interferon treatment without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) for 24 weeks.	
Reporting group title	Arm D
Reporting group description:	
Liver transplant recipients with HCV genotype 1a infection with Child Pugh A cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) plus weight-based ribavirin (dosed 1,000 or 1,200 mg daily divided twice a day) for 24 weeks.	
Reporting group title	Arm E
Reporting group description:	
Liver transplant recipients with HCV genotype 1b infection with Child Pugh A cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 12 weeks.	
Reporting group title	Arm F
Reporting group description:	
Liver transplant recipients with HCV genotype 1a infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 12 weeks.	
Reporting group title	Arm G
Reporting group description:	
Liver transplant recipients with HCV genotype 1b infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) for 12 weeks.	
Reporting group title	Arm H
Reporting group description:	
Renal transplant recipients with HCV genotype 1a infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 12 weeks.	
Reporting group title	Arm I
Reporting group description:	
Renal transplant recipients with HCV genotype 1b infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) for 12 weeks.	
Reporting group title	Arm J
Reporting group description:	
Liver transplant recipients with HCV genotype 4 infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 12 weeks.	
Reporting group title	Arm K
Reporting group description:	
Liver transplant recipients with HCV genotype 4 infection with Child Pugh A cirrhosis received	

ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 24 weeks.

Primary: Percentage of Participants With Sustained Virologic Response 12 Weeks Post-treatment (SVR12)

End point title	Percentage of Participants With Sustained Virologic Response 12 Weeks Post-treatment (SVR12)[1]

End point description:

SVR12 was defined as plasma hepatitis C virus ribonucleic acid (HCV RNA) level less than the lower limit of quantification [<LLOQ]) 12 weeks after the last dose of study drug. Participants with missing data after backward imputation were imputed as nonresponders.

End point type	Primary

End point timeframe:

12 weeks after the last actual dose of study drug

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: Descriptive data are summarized for this end point per protocol.

End point values	Arm A	Arm B	Arm C	Arm D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34[2]	27[3]	13[4]	4[5]
Units: percentage of participants				
number (confidence interval 95%)	97.1 (85.1 to 99.5)	96.3 (81.7 to 99.3)	100 (77.2 to 100)	100 (51 to 100)

Notes:

[2] - All participants who received at least 1 dose of study drug (ITT population).

[3] - All participants who received at least 1 dose of study drug (ITT population).

[4] - All participants who received at least 1 dose of study drug (ITT population).

[5] - All participants who received at least 1 dose of study drug (ITT population).

End point values	Arm E	Arm F	Arm G	Arm H
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2[6]	22[7]	12[8]	9[9]
Units: percentage of participants				
number (confidence interval 95%)	100 (34.2 to 100)	95.5 (78.2 to 99.2)	100 (75.8 to 100)	66.7 (35.4 to 87.9)

Notes:

[6] - All participants who received at least 1 dose of study drug (ITT population).

[7] - All participants who received at least 1 dose of study drug (ITT population).

[8] - All participants who received at least 1 dose of study drug (ITT population).

[9] - All participants who received at least 1 dose of study drug (ITT population).

End point values	Arm I	Arm J	Arm K	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3[10]	2[11]	1[12]	
Units: percentage of participants				
number (confidence interval 95%)	100 (43.9 to 100)	100 (34.2 to 100)	100 (20.7 to 100)	

Notes:

[10] - All participants who received at least 1 dose of study drug (ITT population).

[11] - All participants who received at least 1 dose of study drug (ITT population).

[12] - All participants who received at least 1 dose of study drug (ITT population).

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Sustained Virologic Response 24 Weeks Post-treatment (SVR24)

End point title	Percentage of Participants With Sustained Virologic Response 24 Weeks Post-treatment (SVR24)

End point description:

SVR24 was defined as plasma hepatitis C virus ribonucleic acid (HCV RNA) level less than the lower limit of quantification [<LLOQ]) 24 weeks after the last dose of study drug. Participants with missing data after backward imputation were imputed as nonresponders.

End point type	Secondary

End point timeframe:

24 weeks after the last actual dose of study drug

End point values	Arm A	Arm B	Arm C	Arm D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34[13]	27[14]	13[15]	4[16]
Units: percentage of participants				
number (confidence interval 95%)	97.1 (85.1 to 99.5)	96.3 (81.7 to 99.3)	100 (77.2 to 100)	100 (51 to 100)

Notes:

[13] - All participants who received at least 1 dose of study drug (ITT population).

[14] - All participants who received at least 1 dose of study drug (ITT population).

[15] - All participants who received at least 1 dose of study drug (ITT population).

[16] - All participants who received at least 1 dose of study drug (ITT population).

End point values	Arm E	Arm F	Arm G	Arm H
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2[17]	22[18]	12[19]	9[20]
Units: percentage of participants				
number (confidence interval 95%)	100 (34.2 to 100)	95.5 (78.2 to 99.2)	100 (75.8 to 100)	66.7 (35.4 to 87.9)

Notes:

[17] - All participants who received at least 1 dose of study drug (ITT population).

[18] - All participants who received at least 1 dose of study drug (ITT population).

[19] - All participants who received at least 1 dose of study drug (ITT population).

[20] - All participants who received at least 1 dose of study drug (ITT population).

End point values	Arm I	Arm J	Arm K	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3[21]	2[22]	1[23]	

Units: percentage of participants				
number (confidence interval 95%)	100 (43.9 to 100)	100 (34.2 to 100)	100 (20.7 to 100)	

Notes:

[21] - All participants who received at least 1 dose of study drug (ITT population).

[22] - All participants who received at least 1 dose of study drug (ITT population).

[23] - All participants who received at least 1 dose of study drug (ITT population).

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With On-treatment Virologic Failure

End point title	Percentage of Participants With On-treatment Virologic Failure

End point description:

On-treatment virologic failure was defined as confirmed increase of > 1 log(subscript)10(subscript) IU/mL above the lowest value post-baseline HCV RNA during treatment, or confirmed HCV RNA ≥ LLOQ at any point during treatment after HCV RNA < LLOQ, or HCV RNA ≥ LLOQ persistently during treatment with at least 6 weeks (≥ 36 days) of treatment.

End point type	Secondary

End point timeframe:

Up to 12 weeks (for 12-week treatment) or 24 weeks (for 24-week treatment)

End point values	Arm A	Arm B	Arm C	Arm D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34[24]	27[25]	13[26]	4[27]
Units: percentage of participants				
number (confidence interval 95%)	0 (0 to 10.2)	3.7 (0.7 to 18.3)	0 (0 to 22.8)	0 (0 to 49)

Notes:

[24] - All participants who received at least 1 dose of study drug (ITT population).

[25] - All participants who received at least 1 dose of study drug (ITT population).

[26] - All participants who received at least 1 dose of study drug (ITT population).

[27] - All participants who received at least 1 dose of study drug (ITT population).

End point values	Arm E	Arm F	Arm G	Arm H
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2[28]	22[29]	12[30]	9[31]
Units: percentage of participants				
number (confidence interval 95%)	0 (0 to 65.8)	0 (0 to 14.9)	0 (0 to 24.2)	0 (0 to 29.9)

Notes:

[28] - All participants who received at least 1 dose of study drug (ITT population).

[29] - All participants who received at least 1 dose of study drug (ITT population).

[30] - All participants who received at least 1 dose of study drug (ITT population).

[31] - All participants who received at least 1 dose of study drug (ITT population).

End point values	Arm I	Arm J	Arm K	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3[32]	2[33]	1[34]	
Units: percentage of participants				

number (confidence interval 95%)	0 (0 to 56.1)	0 (0 to 65.8)	0 (0 to 79.3)	

Notes:

[32] - All participants who received at least 1 dose of study drug (ITT population).

[33] - All participants who received at least 1 dose of study drug (ITT population).

[34] - All participants who received at least 1 dose of study drug (ITT population).

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Post-treatment Relapse

End point title	Percentage of Participants With Post-treatment Relapse

End point description:

Post-treatment relapse was defined as confirmed HCV RNA ≥ LLOQ between the end of treatment and 12 weeks after the last dose of study drug among participants who completed treatment with HCV RNA levels < LLOQ at the end of treatment.

End point type	Secondary

End point timeframe:

From the end of treatment through 12 weeks after the last dose of study drug

End point values	Arm A	Arm B	Arm C	Arm D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	33[35]	26[36]	12[37]	4[38]
Units: percentage of participants				
number (confidence interval 95%)	3 (0.5 to 15.3)	0 (0 to 12.9)	0 (0 to 24.2)	0 (0 to 49)

Notes:

[35] - Participants received ≥1 dose, completed treatment, had HCV RNA <LLOQ at the final treatment visit

[36] - Participants received ≥1 dose, completed treatment, had HCV RNA <LLOQ at the final treatment visit

[37] - Participants received ≥1 dose, completed treatment, had HCV RNA <LLOQ at the final treatment visit

[38] - Participants received ≥1 dose, completed treatment, had HCV RNA <LLOQ at the final treatment visit

End point values	Arm E	Arm F	Arm G	Arm H
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2[39]	21[40]	12[41]	6[42]
Units: percentage of participants				
number (confidence interval 95%)	0 (0 to 65.8)	4.8 (0.8 to 22.7)	0 (0 to 24.2)	0 (0 to 39)

Notes:

[39] - Participants received ≥1 dose, completed treatment, had HCV RNA <LLOQ at the final treatment visit

[40] - Participants received ≥1 dose, completed treatment, had HCV RNA <LLOQ at the final treatment visit

[41] - Participants received ≥1 dose, completed treatment, had HCV RNA <LLOQ at the final treatment visit

[42] - Participants received ≥1 dose, completed treatment, had HCV RNA <LLOQ at the final treatment visit

End point values	Arm I	Arm J	Arm K	

Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3[43]	2[44]	1[45]	
Units: percentage of participants				
number (confidence interval 95%)	0 (0 to 56.1)	0 (0 to 65.8)	0 (0 to 79.3)	

Notes:

[43] - Participants received ≥1 dose, completed treatment, had HCV RNA <LLOQ at the final treatment visit

[44] - Participants received ≥1 dose, completed treatment, had HCV RNA <LLOQ at the final treatment visit

[45] - Participants received ≥1 dose, completed treatment, had HCV RNA <LLOQ at the final treatment visit

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Treatment-emergent adverse events (TEAEs) and serious adverse events (TESAEs) were collected from first dose of study drug until 30 days after the last dose of study drug (up to 28 weeks).

Adverse event reporting additional description:

TEAEs and SAEs are defined as any AE or SAE with onset or worsening reported by a participant from the time that the first dose of study drug is administered until 30 days after the last dose of study drug. TEAEs and TESAEs were collected whether elicited or spontaneously reported by the participant.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.0

Reporting groups

Reporting group title	Arm A

Reporting group description:

Liver transplant recipients with HCV genotype 1 infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 24 weeks.

Reporting group title	Arm B

Reporting group description:

Liver transplant recipients with HCV genotype 1a or genotype 1b (dependent on prior treatment experience and response) infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 24 weeks.

Reporting group title	Arm C

Reporting group description:

Liver transplant receipts with HCV genotype 1b infection who were treatment naïve or prior responders to interferon treatment without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) for 24 weeks.

Reporting group title	Arm D

Reporting group description:

Liver transplant recipients with HCV genotype 1a infection with Child Pugh A cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) plus weight-based ribavirin (dosed 1,000 or 1,200 mg daily divided twice a day) for 24 weeks.

Reporting group title	Arm E

Reporting group description:

Liver transplant recipients with HCV genotype 1b infection with Child Pugh A cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 12 weeks.

Reporting group title	Arm F

Reporting group description:

Liver transplant recipients with HCV genotype 1a infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 12 weeks.

Reporting group title	Arm H

Reporting group description:

Renal transplant recipients with HCV genotype 1a infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 12 weeks.

Reporting group title	Arm G

Reporting group description:

Liver transplant recipients with HCV genotype 1b infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) for 12 weeks.

Reporting group title	Arm J

Reporting group description:

Liver transplant recipients with HCV genotype 4 infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 12 weeks.

Reporting group title	Arm I

Reporting group description:

Renal transplant recipients with HCV genotype 1b infection without cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) with dasabuvir (250 mg twice daily) for 12 weeks.

Reporting group title	Arm K

Reporting group description:

Liver transplant recipients with HCV genotype 4 infection with Child Pugh A cirrhosis received ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) plus weight-based ribavirin (1,000 or 1,200 mg daily divided twice a day) for 24 weeks.

Serious adverse events	Arm A	Arm B	Arm C
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 34 (5.88%)	1 / 27 (3.70%)	0 / 13 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
OVERDOSE			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
HYPOTENSION			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
TACHYCARDIA			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (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
Nervous system disorders			
ISCHAEMIC CEREBRAL INFARCTION			

subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSIENT ISCHAEMIC ATTACK			
subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
LEUKOCYTOSIS			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
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			
OEDEMA PERIPHERAL			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
NAUSEA			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
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 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
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			
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			

subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
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 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
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			
PAIN IN EXTREMITY			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (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			
ATYPICAL PNEUMONIA			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
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 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
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			
HYPONATRAEMIA			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
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	Arm D	Arm E	Arm F
Total subjects affected by serious adverse events			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 22 (9.09%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
OVERDOSE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
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 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
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			
TACHYCARDIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
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			
ISCHAEMIC CEREBRAL INFARCTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSIENT ISCHAEMIC ATTACK			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
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			
LEUKOCYTOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
OEDEMA PERIPHERAL			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
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			
NAUSEA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
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 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
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, thoracic and mediastinal disorders			
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
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 and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
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			
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
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			
ATYPICAL PNEUMONIA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
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			
HYPONATRAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
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	Arm H	Arm G	Arm J
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 9 (44.44%)	1 / 12 (8.33%)	0 / 2 (0.00%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
OVERDOSE			
subjects affected / exposed	1 / 9 (11.11%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Vascular disorders			
HYPOTENSION			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
TACHYCARDIA			

subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
ISCHAEMIC CEREBRAL INFARCTION			
subjects affected / exposed	1 / 9 (11.11%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSIENT ISCHAEMIC ATTACK			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
LEUKOCYTOSIS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
NAUSEA			
subjects affected / exposed	1 / 9 (11.11%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			
subjects affected / exposed	1 / 9 (11.11%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
ACUTE RESPIRATORY FAILURE			

subjects affected / exposed	1 / 9 (11.11%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	1 / 9 (11.11%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
ATYPICAL PNEUMONIA			
subjects affected / exposed	1 / 9 (11.11%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
HYPONATRAEMIA			

subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Arm I	Arm K	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
OVERDOSE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (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 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
TACHYCARDIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
ISCHAEMIC CEREBRAL INFARCTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRANSIENT ISCHAEMIC ATTACK			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (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			
LEUKOCYTOSIS			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (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			
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
NAUSEA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (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 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (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 / 3 (0.00%)	0 / 1 (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			
PAIN IN EXTREMITY			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
ATYPICAL PNEUMONIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
HYPONATRAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (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: 0 %

Non-serious adverse events	Arm A	Arm B	Arm C
Total subjects affected by non-serious adverse events			
subjects affected / exposed	33 / 34 (97.06%)	27 / 27 (100.00%)	12 / 13 (92.31%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
KERATOACANTHOMA			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	0	1	0

Vascular disorders			
HOT FLUSH			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
HYPERTENSION			
subjects affected / exposed	3 / 34 (8.82%)	3 / 27 (11.11%)	1 / 13 (7.69%)
occurrences (all)	3	3	1
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	8 / 34 (23.53%)	7 / 27 (25.93%)	1 / 13 (7.69%)
occurrences (all)	11	13	1
CHEST PAIN			
subjects affected / exposed	0 / 34 (0.00%)	2 / 27 (7.41%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
CHILLS			
subjects affected / exposed	2 / 34 (5.88%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	2	1	0
EXERCISE TOLERANCE DECREASED			
subjects affected / exposed	2 / 34 (5.88%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
FACE OEDEMA			
subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
FATIGUE			
subjects affected / exposed	17 / 34 (50.00%)	14 / 27 (51.85%)	4 / 13 (30.77%)
occurrences (all)	20	16	4
FEELING ABNORMAL			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
FEELING COLD			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
HERNIA PAIN			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
INFLUENZA LIKE ILLNESS			

subjects affected / exposed	2 / 34 (5.88%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	2	1	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
OEDEMA			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
OEDEMA PERIPHERAL			
subjects affected / exposed	5 / 34 (14.71%)	2 / 27 (7.41%)	1 / 13 (7.69%)
occurrences (all)	5	2	1
PAIN			
subjects affected / exposed	3 / 34 (8.82%)	2 / 27 (7.41%)	0 / 13 (0.00%)
occurrences (all)	3	3	0
PERIPHERAL SWELLING			
subjects affected / exposed	0 / 34 (0.00%)	2 / 27 (7.41%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
PYREXIA			
subjects affected / exposed	5 / 34 (14.71%)	2 / 27 (7.41%)	0 / 13 (0.00%)
occurrences (all)	7	2	0
Immune system disorders			
ALLERGY TO ARTHROPOD BITE			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
LIVER TRANSPLANT REJECTION			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
SEASONAL ALLERGY			
subjects affected / exposed	2 / 34 (5.88%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Reproductive system and breast disorders			
ERECTILE DYSFUNCTION			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
GENITAL RASH			

subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
PENILE BLISTER			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
PROSTATITIS			
subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
PROSTATOMEGALY			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL PRURITUS			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
CHOKING			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
COUGH			
subjects affected / exposed	11 / 34 (32.35%)	5 / 27 (18.52%)	2 / 13 (15.38%)
occurrences (all)	14	6	3
DRY THROAT			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
DYSPHONIA			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
DYSPNOEA			
subjects affected / exposed	3 / 34 (8.82%)	3 / 27 (11.11%)	0 / 13 (0.00%)
occurrences (all)	4	4	0
DYSPNOEA EXERTIONAL			
subjects affected / exposed	5 / 34 (14.71%)	5 / 27 (18.52%)	0 / 13 (0.00%)
occurrences (all)	5	5	0
NASAL CONGESTION			

subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	3 / 34 (8.82%)	1 / 27 (3.70%)	1 / 13 (7.69%)
occurrences (all)	3	1	1
PARANASAL SINUS DISCOMFORT			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
PRODUCTIVE COUGH			
subjects affected / exposed	2 / 34 (5.88%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	3	2	0
RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	1 / 34 (2.94%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	3	1	0
RHINORRHOEA			
subjects affected / exposed	6 / 34 (17.65%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	6	0	0
SINUS CONGESTION			
subjects affected / exposed	2 / 34 (5.88%)	1 / 27 (3.70%)	1 / 13 (7.69%)
occurrences (all)	2	2	1
SNEEZING			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
THROAT IRRITATION			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
UPPER RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
WHEEZING			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0

Psychiatric disorders			
ABNORMAL DREAMS			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
AFFECT LABILITY			
subjects affected / exposed	3 / 34 (8.82%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	3	0	0
ANXIETY			
subjects affected / exposed	5 / 34 (14.71%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	5	0	0
APATHY			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
DEPRESSED MOOD			
subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
DEPRESSION			
subjects affected / exposed	4 / 34 (11.76%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	4	1	0
EMOTIONAL DISORDER			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
INSOMNIA			
subjects affected / exposed	9 / 34 (26.47%)	3 / 27 (11.11%)	0 / 13 (0.00%)
occurrences (all)	9	3	0
IRRITABILITY			
subjects affected / exposed	4 / 34 (11.76%)	2 / 27 (7.41%)	0 / 13 (0.00%)
occurrences (all)	4	2	0
LIBIDO INCREASED			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
MANIA			

subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
MOOD SWINGS			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
NIGHTMARE			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
RESTLESSNESS			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
BLOOD BICARBONATE DECREASED			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	1 / 34 (2.94%)	1 / 27 (3.70%)	1 / 13 (7.69%)
occurrences (all)	1	1	1
BLOOD GLUCOSE INCREASED			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
BLOOD POTASSIUM INCREASED			

subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
BLOOD PRESSURE INCREASED			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
BLOOD TRIGLYCERIDES INCREASED			
subjects affected / exposed	2 / 34 (5.88%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
BLOOD UREA INCREASED			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
BLOOD URINE PRESENT			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
CARDIAC MURMUR			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
CYTOMEGALOVIRUS TEST POSITIVE			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
HAEMATOCRIT DECREASED			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
HAEMOGLOBIN DECREASED			
subjects affected / exposed	1 / 34 (2.94%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	2	1	0
IMMUNOSUPPRESSANT DRUG LEVEL INCREASED			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
LYMPHOCYTE COUNT DECREASED			

subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
VITAMIN D DECREASED			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
WEIGHT DECREASED			
subjects affected / exposed	3 / 34 (8.82%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	3	1	0
WEIGHT INCREASED			
subjects affected / exposed	1 / 34 (2.94%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
ACCIDENT			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
ARTHROPOD BITE			
subjects affected / exposed	2 / 34 (5.88%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
ARTHROPOD STING			
subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
CONTUSION			
subjects affected / exposed	2 / 34 (5.88%)	1 / 27 (3.70%)	1 / 13 (7.69%)
occurrences (all)	2	1	1
EXCORIATION			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
FALL			

subjects affected / exposed	2 / 34 (5.88%)	0 / 27 (0.00%)	1 / 13 (7.69%)
occurrences (all)	2	0	1
FEMORAL NECK FRACTURE			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
JOINT INJURY			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
LACERATION			
subjects affected / exposed	0 / 34 (0.00%)	2 / 27 (7.41%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
MUSCLE STRAIN			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
OVERDOSE			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
POST-TRAUMATIC NECK SYNDROME			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
SCRATCH			
subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
SUNBURN			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
SUPERFICIAL INJURY OF EYE			
subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
TOOTH FRACTURE			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
TRAUMATIC FRACTURE			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Cardiac disorders			

PALPITATIONS			
subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
BALANCE DISORDER			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
CAROTID ARTERY STENOSIS			
subjects affected / exposed	1 / 34 (2.94%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
DIZZINESS			
subjects affected / exposed	6 / 34 (17.65%)	4 / 27 (14.81%)	1 / 13 (7.69%)
occurrences (all)	7	4	1
DYSGEUSIA			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
HEADACHE			
subjects affected / exposed	15 / 34 (44.12%)	8 / 27 (29.63%)	2 / 13 (15.38%)
occurrences (all)	20	9	3
HYPERSOMNIA			
subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
HYPOAESTHESIA			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
MEMORY IMPAIRMENT			
subjects affected / exposed	2 / 34 (5.88%)	1 / 27 (3.70%)	1 / 13 (7.69%)
occurrences (all)	2	1	1
MIGRAINE			
subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
ORTHOSTATIC INTOLERANCE			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
PARAESTHESIA			

subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
POOR QUALITY SLEEP			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
PRESYNCOPE			
subjects affected / exposed	2 / 34 (5.88%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
SEIZURE			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
SINUS HEADACHE			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
SYNCOPE			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
TENSION HEADACHE			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
TREMOR			
subjects affected / exposed	1 / 34 (2.94%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
TUNNEL VISION			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	8 / 34 (23.53%)	8 / 27 (29.63%)	1 / 13 (7.69%)
occurrences (all)	8	9	1
HAEMOLYTIC ANAEMIA			
subjects affected / exposed	2 / 34 (5.88%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
LEUKOPENIA			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0

LYMPHOPENIA			
subjects affected / exposed	2 / 34 (5.88%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Ear and labyrinth disorders			
EAR PAIN			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
VERTIGO			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Eye disorders			
DIPLOPIA			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
DRY EYE			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
EYE PAIN			
subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
EYE PRURITUS			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
OCULAR DISCOMFORT			
subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
OCULAR HYPERAEMIA			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
VISION BLURRED			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
VISUAL IMPAIRMENT			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
VITREOUS FLOATERS			

subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	2 / 34 (5.88%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
ABDOMINAL DISTENSION			
subjects affected / exposed	3 / 34 (8.82%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	3	1	0
ABDOMINAL PAIN			
subjects affected / exposed	5 / 34 (14.71%)	0 / 27 (0.00%)	1 / 13 (7.69%)
occurrences (all)	5	0	1
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	4 / 34 (11.76%)	2 / 27 (7.41%)	1 / 13 (7.69%)
occurrences (all)	4	2	1
ANAL PRURITUS			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
ANORECTAL DISCOMFORT			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
APHTHOUS ULCER			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
BOWEL MOVEMENT IRREGULARITY			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
CONSTIPATION			
subjects affected / exposed	2 / 34 (5.88%)	1 / 27 (3.70%)	1 / 13 (7.69%)
occurrences (all)	2	1	1
DENTAL CARIES			
subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	0	2	0

DIARRHOEA			
subjects affected / exposed	9 / 34 (26.47%)	6 / 27 (22.22%)	1 / 13 (7.69%)
occurrences (all)	17	7	1
DIVERTICULUM INTESTINAL			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
DRY MOUTH			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
DYSPEPSIA			
subjects affected / exposed	3 / 34 (8.82%)	1 / 27 (3.70%)	1 / 13 (7.69%)
occurrences (all)	3	2	1
DYSPHAGIA			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
EPIGASTRIC DISCOMFORT			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
FAECES DISCOLOURED			
subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
FLATULENCE			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	1 / 34 (2.94%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
GINGIVAL BLEEDING			
subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
HAEMORRHOIDS			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
LIP DRY			

subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
NAUSEA			
subjects affected / exposed	8 / 34 (23.53%)	11 / 27 (40.74%)	2 / 13 (15.38%)
occurrences (all)	9	14	2
OESOPHAGEAL DILATATION			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
TOOTH IMPACTED			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
TOOTHACHE			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
VOMITING			
subjects affected / exposed	4 / 34 (11.76%)	5 / 27 (18.52%)	0 / 13 (0.00%)
occurrences (all)	6	8	0
Hepatobiliary disorders			
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
JAUNDICE			
subjects affected / exposed	0 / 34 (0.00%)	3 / 27 (11.11%)	0 / 13 (0.00%)
occurrences (all)	0	6	0
Skin and subcutaneous tissue disorders			
ACNE			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
ALOPECIA			
subjects affected / exposed	0 / 34 (0.00%)	2 / 27 (7.41%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
DERMATITIS CONTACT			

subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
DRY SKIN			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
ERYTHEMA			
subjects affected / exposed	3 / 34 (8.82%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	4	1	0
HAIR GROWTH ABNORMAL			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
PETECHIAE			
subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
PHOTOSENSITIVITY REACTION			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
PRURITUS			
subjects affected / exposed	2 / 34 (5.88%)	4 / 27 (14.81%)	1 / 13 (7.69%)
occurrences (all)	2	6	1
PRURITUS GENERALISED			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
PSORIASIS			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
RASH			
subjects affected / exposed	7 / 34 (20.59%)	9 / 27 (33.33%)	0 / 13 (0.00%)
occurrences (all)	10	12	0
RASH GENERALISED			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
RASH MACULAR			

subjects affected / exposed	1 / 34 (2.94%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
RASH PAPULAR			
subjects affected / exposed	2 / 34 (5.88%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	3	0	0
RASH PRURITIC			
subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
SKIN EXFOLIATION			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
SKIN LESION			
subjects affected / exposed	1 / 34 (2.94%)	2 / 27 (7.41%)	0 / 13 (0.00%)
occurrences (all)	1	2	0
SKIN TIGHTNESS			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
URTICARIA			
subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
ANURIA			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
CHROMATURIA			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
DYSURIA			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
POLLAKIURIA			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

POLYURIA			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
PROTEINURIA			
subjects affected / exposed	2 / 34 (5.88%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
URINARY RETENTION			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	2 / 34 (5.88%)	2 / 27 (7.41%)	0 / 13 (0.00%)
occurrences (all)	2	2	0
ARTHRITIS			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
BACK PAIN			
subjects affected / exposed	6 / 34 (17.65%)	0 / 27 (0.00%)	1 / 13 (7.69%)
occurrences (all)	7	0	1
FLANK PAIN			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
GOUTY ARTHRITIS			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
GROIN PAIN			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
LIMB DISCOMFORT			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
MUSCLE FATIGUE			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
MUSCLE SPASMS			

subjects affected / exposed	7 / 34 (20.59%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	8	1	0
MUSCLE TWITCHING			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
MUSCULOSKELETAL DISCOMFORT			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MYALGIA			
subjects affected / exposed	3 / 34 (8.82%)	4 / 27 (14.81%)	0 / 13 (0.00%)
occurrences (all)	4	4	0
NECK PAIN			
subjects affected / exposed	1 / 34 (2.94%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
PAIN IN EXTREMITY			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
TENDONITIS			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
ACARODERMATITIS			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
CELLULITIS			
subjects affected / exposed	1 / 34 (2.94%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
CYTOMEGALOVIRUS VIRAEMIA			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
FOLLICULITIS			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0

FUNGAL INFECTION			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
GASTROENTERITIS			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
HERPES ZOSTER			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
HORDEOLUM			
subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
IMPETIGO			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
INFLUENZA			
subjects affected / exposed	2 / 34 (5.88%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	2	1	0
LOCALISED INFECTION			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
ORAL HERPES			
subjects affected / exposed	1 / 34 (2.94%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
OTITIS MEDIA			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
PHARYNGITIS			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
PHARYNGITIS STREPTOCOCCAL			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0

SINUSITIS			
subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
SKIN INFECTION			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
TINEA CRURIS			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
TINEA PEDIS			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
TOOTH INFECTION			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	2 / 34 (5.88%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	2	1	0
URINARY TRACT INFECTION			
subjects affected / exposed	4 / 34 (11.76%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	5	1	0
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	3 / 34 (8.82%)	2 / 27 (7.41%)	2 / 13 (15.38%)
occurrences (all)	3	2	2
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	4 / 34 (11.76%)	3 / 27 (11.11%)	1 / 13 (7.69%)
occurrences (all)	5	3	1
DEHYDRATION			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
DIABETES MELLITUS			
subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
DIABETES MELLITUS INADEQUATE CONTROL			

subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
GOUT			
subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	1 / 13 (7.69%)
occurrences (all)	0	1	2
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 34 (0.00%)	1 / 27 (3.70%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
HYPERKALAEMIA			
subjects affected / exposed	2 / 34 (5.88%)	0 / 27 (0.00%)	2 / 13 (15.38%)
occurrences (all)	2	0	2
HYPERURICAEMIA			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
HYPOMAGNESAEMIA			
subjects affected / exposed	1 / 34 (2.94%)	0 / 27 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
HYPONATRAEMIA			
subjects affected / exposed	0 / 34 (0.00%)	0 / 27 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1

Non-serious adverse events	Arm D	Arm E	Arm F
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	2 / 2 (100.00%)	22 / 22 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
KERATOACANTHOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SQUAMOUS CELL CARCINOMA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
HOT FLUSH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPERTENSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	0 / 4 (0.00%)	2 / 2 (100.00%)	2 / 22 (9.09%)
occurrences (all)	0	3	2
CHEST PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
CHILLS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
EXERCISE TOLERANCE DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
FACE OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
FATIGUE			
subjects affected / exposed	4 / 4 (100.00%)	0 / 2 (0.00%)	14 / 22 (63.64%)
occurrences (all)	8	0	14
FEELING ABNORMAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
FEELING COLD			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HERNIA PAIN			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
OEDEMA PERIPHERAL			
subjects affected / exposed	1 / 4 (25.00%)	1 / 2 (50.00%)	1 / 22 (4.55%)
occurrences (all)	2	1	1
PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
PERIPHERAL SWELLING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PYREXIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
ALLERGY TO ARTHROPOD BITE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
LIVER TRANSPLANT REJECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SEASONAL ALLERGY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

ERECTILE DYSFUNCTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
GENITAL RASH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PENILE BLISTER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PROSTATITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PROSTATOMEGALY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL PRURITUS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
CHOKING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
COUGH			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	3 / 22 (13.64%)
occurrences (all)	0	1	3
DRY THROAT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
DYSPHONIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
DYSPNOEA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	2 / 22 (9.09%)
occurrences (all)	3	0	6
DYSPNOEA EXERTIONAL			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
NASAL CONGESTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	3 / 22 (13.64%)
occurrences (all)	0	0	4
PARANASAL SINUS DISCOMFORT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	3 / 22 (13.64%)
occurrences (all)	0	0	3
RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
RHINORRHOEA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
SINUS CONGESTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SNEEZING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
THROAT IRRITATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1

WHEEZING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
ABNORMAL DREAMS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
AFFECT LABILITY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
ANXIETY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
APATHY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
DEPRESSED MOOD			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
DEPRESSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
EMOTIONAL DISORDER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
INSOMNIA			
subjects affected / exposed	1 / 4 (25.00%)	1 / 2 (50.00%)	3 / 22 (13.64%)
occurrences (all)	1	1	3
IRRITABILITY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
LIBIDO INCREASED			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
MANIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
MOOD SWINGS			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
NIGHTMARE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
RESTLESSNESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
BLOOD BICARBONATE DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	2
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
BLOOD GLUCOSE INCREASED			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
BLOOD POTASSIUM INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
BLOOD PRESSURE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
BLOOD TRIGLYCERIDES INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
BLOOD UREA INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
BLOOD URINE PRESENT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
CARDIAC MURMUR			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
CYTOMEGALOVIRUS TEST POSITIVE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HAEMATOCRIT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HAEMOGLOBIN DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
IMMUNOSUPPRESSANT DRUG LEVEL INCREASED			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
VITAMIN D DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
WEIGHT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
WEIGHT INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
ACCIDENT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
ARTHROPOD BITE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
ARTHROPOD STING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
CONTUSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
EXCORIATION			

subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
FALL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
FEMORAL NECK FRACTURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
JOINT INJURY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
LACERATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
MUSCLE STRAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
OVERDOSE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
POST-TRAUMATIC NECK SYNDROME			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SCRATCH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SUNBURN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SUPERFICIAL INJURY OF EYE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
TOOTH FRACTURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
TRAUMATIC FRACTURE			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
PALPITATIONS			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
BALANCE DISORDER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
CAROTID ARTERY STENOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
DIZZINESS			
subjects affected / exposed	1 / 4 (25.00%)	1 / 2 (50.00%)	4 / 22 (18.18%)
occurrences (all)	1	1	4
DYSGEUSIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HEADACHE			
subjects affected / exposed	2 / 4 (50.00%)	1 / 2 (50.00%)	6 / 22 (27.27%)
occurrences (all)	3	2	6
HYPERSOMNIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPOAESTHESIA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
MEMORY IMPAIRMENT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
MIGRAINE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
ORTHOSTATIC INTOLERANCE			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PARAESTHESIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
POOR QUALITY SLEEP			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PRESYNCOPE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SEIZURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SINUS HEADACHE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SYNCOPE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
TENSION HEADACHE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
TREMOR			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
TUNNEL VISION			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	3 / 4 (75.00%)	2 / 2 (100.00%)	4 / 22 (18.18%)
occurrences (all)	3	3	4
HAEMOLYTIC ANAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1

LEUKOPENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
LYMPHOPENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
EAR PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
VERTIGO			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
DIPLOPIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
DRY EYE			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
EYE PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
EYE PRURITUS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
OCULAR DISCOMFORT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
OCULAR HYPERAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
VISUAL IMPAIRMENT			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
VITREOUS FLOATERS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	3 / 22 (13.64%)
occurrences (all)	0	0	3
ABDOMINAL DISTENSION			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
ABDOMINAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
ANAL PRURITUS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
ANORECTAL DISCOMFORT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
APHTHOUS ULCER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
BOWEL MOVEMENT IRREGULARITY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
CONSTIPATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	4 / 22 (18.18%)
occurrences (all)	0	0	4

DENTAL CARIES			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
DIARRHOEA			
subjects affected / exposed	1 / 4 (25.00%)	1 / 2 (50.00%)	6 / 22 (27.27%)
occurrences (all)	1	1	6
DIVERTICULUM INTESTINAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
DRY MOUTH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
DYSPEPSIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
DYSPHAGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
EPIGASTRIC DISCOMFORT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
FAECES DISCOLOURED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
FLATULENCE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
GINGIVAL BLEEDING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HAEMORRHOIDS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
LIP DRY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
NAUSEA			
subjects affected / exposed	2 / 4 (50.00%)	1 / 2 (50.00%)	4 / 22 (18.18%)
occurrences (all)	2	1	4
OESOPHAGEAL DILATATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
TOOTH IMPACTED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
TOOTHACHE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
VOMITING			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
Hepatobiliary disorders			
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
JAUNDICE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
ACNE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
ALOPECIA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
DERMATITIS CONTACT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
DRY SKIN			
subjects affected / exposed	2 / 4 (50.00%)	1 / 2 (50.00%)	1 / 22 (4.55%)
occurrences (all)	4	1	1
ERYTHEMA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
HAIR GROWTH ABNORMAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
PETECHIAE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PHOTOSENSITIVITY REACTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PRURITUS			
subjects affected / exposed	4 / 4 (100.00%)	2 / 2 (100.00%)	5 / 22 (22.73%)
occurrences (all)	8	4	5
PRURITUS GENERALISED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PSORIASIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
RASH			
subjects affected / exposed	2 / 4 (50.00%)	0 / 2 (0.00%)	4 / 22 (18.18%)
occurrences (all)	4	0	4
RASH GENERALISED			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
RASH MACULAR			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
RASH PAPULAR			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
RASH PRURITIC			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
SKIN EXFOLIATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SKIN LESION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SKIN TIGHTNESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
URTICARIA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
ANURIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
CHROMATURIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
DYSURIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

POLLAKIURIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
POLYURIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PROTEINURIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
URINARY RETENTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
ARTHRITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
BACK PAIN			
subjects affected / exposed	2 / 4 (50.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	2	0	1
FLANK PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
GOUTY ARTHRITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
GROIN PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
LIMB DISCOMFORT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
MUSCLE FATIGUE			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
MUSCLE TWITCHING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL DISCOMFORT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
MYALGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
NECK PAIN			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
TENDONITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
ACARODERMATITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
CELLULITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
CYTOMEGALOVIRUS VIRAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1

FOLLICULITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
FUNGAL INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HERPES ZOSTER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HORDEOLUM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
IMPETIGO			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
INFLUENZA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
LOCALISED INFECTION			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
ORAL HERPES			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
OTITIS MEDIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

PHARYNGITIS STREPTOCOCCAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SINUSITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SKIN INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
TINEA CRURIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
TINEA PEDIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
TOOTH INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	1 / 4 (25.00%)	1 / 2 (50.00%)	0 / 22 (0.00%)
occurrences (all)	1	1	0
DEHYDRATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
DIABETES MELLITUS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
DIABETES MELLITUS INADEQUATE CONTROL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
GOUT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
HYPERKALAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
HYPERURICAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPONATRAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Arm H	Arm G	Arm J
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 9 (88.89%)	12 / 12 (100.00%)	2 / 2 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

KERATOACANTHOMA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
HOT FLUSH			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPERTENSION			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
CHEST PAIN			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CHILLS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
EXERCISE TOLERANCE DECREASED			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
FACE OEDEMA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
FATIGUE			
subjects affected / exposed	6 / 9 (66.67%)	2 / 12 (16.67%)	1 / 2 (50.00%)
occurrences (all)	6	2	1
FEELING ABNORMAL			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
FEELING COLD			

subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HERNIA PAIN			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
OEDEMA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
PAIN			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
PERIPHERAL SWELLING			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
PYREXIA			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
ALLERGY TO ARTHROPOD BITE			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LIVER TRANSPLANT REJECTION			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SEASONAL ALLERGY			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Reproductive system and breast disorders			
ERECTILE DYSFUNCTION			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GENITAL RASH			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PENILE BLISTER			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PROSTATITIS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PROSTATOMEGALY			
subjects affected / exposed	1 / 9 (11.11%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
VULVOVAGINAL PRURITUS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
CHOKING			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
COUGH			
subjects affected / exposed	3 / 9 (33.33%)	1 / 12 (8.33%)	1 / 2 (50.00%)
occurrences (all)	3	1	1
DRY THROAT			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DYSPHONIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DYSPNOEA			
subjects affected / exposed	1 / 9 (11.11%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
DYSPNOEA EXERTIONAL			

subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
NASAL CONGESTION			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
PARANASAL SINUS DISCOMFORT			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RHINORRHOEA			
subjects affected / exposed	1 / 9 (11.11%)	0 / 12 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	1
SINUS CONGESTION			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
SNEEZING			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
THROAT IRRITATION			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

WHEEZING			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
ABNORMAL DREAMS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
AFFECT LABILITY			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ANXIETY			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
APATHY			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
DEPRESSED MOOD			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
DEPRESSION			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
EMOTIONAL DISORDER			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
INSOMNIA			
subjects affected / exposed	2 / 9 (22.22%)	2 / 12 (16.67%)	0 / 2 (0.00%)
occurrences (all)	2	2	0
IRRITABILITY			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
LIBIDO INCREASED			

subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
MANIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
MOOD SWINGS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
NIGHTMARE			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RESTLESSNESS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BLOOD BICARBONATE DECREASED			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	1 / 9 (11.11%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
BLOOD GLUCOSE INCREASED			

subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BLOOD POTASSIUM INCREASED			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BLOOD PRESSURE INCREASED			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
BLOOD TRIGLYCERIDES INCREASED			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BLOOD UREA INCREASED			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BLOOD URINE PRESENT			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CARDIAC MURMUR			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CYTOMEGALOVIRUS TEST POSITIVE			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HAEMATOCRIT DECREASED			
subjects affected / exposed	1 / 9 (11.11%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
HAEMOGLOBIN DECREASED			
subjects affected / exposed	2 / 9 (22.22%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
IMMUNOSUPPRESSANT DRUG LEVEL INCREASED			

subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
VITAMIN D DECREASED			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
WEIGHT DECREASED			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
WEIGHT INCREASED			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
ACCIDENT			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ARTHROPOD BITE			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ARTHROPOD STING			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CONTUSION			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
EXCORIATION			

subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
FALL			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
FEMORAL NECK FRACTURE			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
JOINT INJURY			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
LACERATION			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
MUSCLE STRAIN			
subjects affected / exposed	1 / 9 (11.11%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
OVERDOSE			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
POST-TRAUMATIC NECK SYNDROME			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SCRATCH			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SUNBURN			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SUPERFICIAL INJURY OF EYE			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
TOOTH FRACTURE			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
TRAUMATIC FRACTURE			

subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
PALPITATIONS			
subjects affected / exposed	1 / 9 (11.11%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
BALANCE DISORDER			
subjects affected / exposed	1 / 9 (11.11%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
CAROTID ARTERY STENOSIS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DIZZINESS			
subjects affected / exposed	1 / 9 (11.11%)	2 / 12 (16.67%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
DYSGEUSIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HEADACHE			
subjects affected / exposed	3 / 9 (33.33%)	6 / 12 (50.00%)	0 / 2 (0.00%)
occurrences (all)	4	7	0
HYPERSOMNIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPOAESTHESIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
MEMORY IMPAIRMENT			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
MIGRAINE			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ORTHOSTATIC INTOLERANCE			

subjects affected / exposed	1 / 9 (11.11%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
PARAESTHESIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
POOR QUALITY SLEEP			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PRESYNCOPE			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
SEIZURE			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SINUS HEADACHE			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SYNCOPE			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
TENSION HEADACHE			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
TREMOR			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
TUNNEL VISION			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	2 / 9 (22.22%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	4	0	0
HAEMOLYTIC ANAEMIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

LEUKOPENIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LYMPHOPENIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
EAR PAIN			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
VERTIGO			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
DIPLOPIA			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
DRY EYE			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
EYE PAIN			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
EYE PRURITUS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
OCULAR DISCOMFORT			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
OCULAR HYPERAEMIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
VISUAL IMPAIRMENT			

subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
VITREOUS FLOATERS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	1 / 9 (11.11%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
ABDOMINAL DISTENSION			
subjects affected / exposed	1 / 9 (11.11%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
ABDOMINAL PAIN			
subjects affected / exposed	0 / 9 (0.00%)	2 / 12 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
ABDOMINAL PAIN LOWER			
subjects affected / exposed	1 / 9 (11.11%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
ANAL PRURITUS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ANORECTAL DISCOMFORT			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
APHTHOUS ULCER			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
BOWEL MOVEMENT IRREGULARITY			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CONSTIPATION			
subjects affected / exposed	2 / 9 (22.22%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	2	1	0

DENTAL CARIES			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DIARRHOEA			
subjects affected / exposed	2 / 9 (22.22%)	2 / 12 (16.67%)	0 / 2 (0.00%)
occurrences (all)	2	2	0
DIVERTICULUM INTESTINAL			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DRY MOUTH			
subjects affected / exposed	1 / 9 (11.11%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
DYSPEPSIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DYSPHAGIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
EPIGASTRIC DISCOMFORT			
subjects affected / exposed	1 / 9 (11.11%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
FAECES DISCOLOURED			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
FLATULENCE			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GINGIVAL BLEEDING			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HAEMORRHOIDS			

subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LIP DRY			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
NAUSEA			
subjects affected / exposed	2 / 9 (22.22%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
OESOPHAGEAL DILATATION			
subjects affected / exposed	1 / 9 (11.11%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	1 / 9 (11.11%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
TOOTH IMPACTED			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
TOOTHACHE			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
VOMITING			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
Hepatobiliary disorders			
HYPERBILIRUBINAEMIA			
subjects affected / exposed	1 / 9 (11.11%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
JAUNDICE			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
ACNE			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ALOPECIA			

subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DERMATITIS CONTACT			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DRY SKIN			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ERYTHEMA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HAIR GROWTH ABNORMAL			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PETECHIAE			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PHOTOSENSITIVITY REACTION			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PRURITUS			
subjects affected / exposed	1 / 9 (11.11%)	4 / 12 (33.33%)	1 / 2 (50.00%)
occurrences (all)	2	4	1
PRURITUS GENERALISED			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
PSORIASIS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RASH			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
RASH GENERALISED			

subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RASH MACULAR			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RASH PAPULAR			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RASH PRURITIC			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SKIN EXFOLIATION			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SKIN LESION			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
SKIN TIGHTNESS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
URTICARIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
ANURIA			
subjects affected / exposed	1 / 9 (11.11%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
CHROMATURIA			
subjects affected / exposed	1 / 9 (11.11%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
DYSURIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

POLLAKIURIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
POLYURIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PROTEINURIA			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
URINARY RETENTION			
subjects affected / exposed	1 / 9 (11.11%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
ARTHRITIS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BACK PAIN			
subjects affected / exposed	1 / 9 (11.11%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
FLANK PAIN			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GOUTY ARTHRITIS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GROIN PAIN			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
LIMB DISCOMFORT			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
MUSCLE FATIGUE			

subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
MUSCLE TWITCHING			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL DISCOMFORT			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
MYALGIA			
subjects affected / exposed	2 / 9 (22.22%)	0 / 12 (0.00%)	1 / 2 (50.00%)
occurrences (all)	2	0	1
NECK PAIN			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
TENDONITIS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
ACARODERMATITIS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CELLULITIS			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
CYTOMEGALOVIRUS VIRAEMIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

FOLLICULITIS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
FUNGAL INFECTION			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HERPES ZOSTER			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HORDEOLUM			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
IMPETIGO			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
INFLUENZA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LOCALISED INFECTION			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ORAL HERPES			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
OTITIS MEDIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

PHARYNGITIS STREPTOCOCCAL			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SINUSITIS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SKIN INFECTION			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
TINEA CRURIS			
subjects affected / exposed	1 / 9 (11.11%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
TINEA PEDIS			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
TOOTH INFECTION			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 9 (11.11%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	2 / 9 (22.22%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
DEHYDRATION			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
DIABETES MELLITUS			

subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DIABETES MELLITUS INADEQUATE CONTROL			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GOUT			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPERKALAEMIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPERURICAEMIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPOGLYCAEMIA			
subjects affected / exposed	1 / 9 (11.11%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
HYPOKALAEMIA			
subjects affected / exposed	0 / 9 (0.00%)	1 / 12 (8.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
HYPOMAGNESAEMIA			
subjects affected / exposed	1 / 9 (11.11%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
HYPONATRAEMIA			
subjects affected / exposed	2 / 9 (22.22%)	0 / 12 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0

Non-serious adverse events	Arm I	Arm K	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	1 / 1 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

KERATOACANTHOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
HOT FLUSH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
HYPERTENSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
CHEST PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
CHILLS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
EXERCISE TOLERANCE DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
FACE OEDEMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
FATIGUE			
subjects affected / exposed	1 / 3 (33.33%)	1 / 1 (100.00%)	
occurrences (all)	1	1	
FEELING ABNORMAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
FEELING COLD			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
HERNIA PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 3 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
OEDEMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
OEDEMA PERIPHERAL			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
PERIPHERAL SWELLING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
PYREXIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
ALLERGY TO ARTHROPOD BITE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
LIVER TRANSPLANT REJECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
SEASONAL ALLERGY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	

Reproductive system and breast disorders			
ERECTILE DYSFUNCTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
GENITAL RASH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
PENILE BLISTER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
PROSTATITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
PROSTATOMEGALY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
VULVOVAGINAL PRURITUS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
CHOKING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
COUGH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
DRY THROAT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
DYSPHONIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
DYSPNOEA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
DYSPNOEA EXERTIONAL			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
NASAL CONGESTION				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
OROPHARYNGEAL PAIN				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
PARANASAL SINUS DISCOMFORT				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
PRODUCTIVE COUGH				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
RESPIRATORY TRACT CONGESTION				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
RHINORRHOEA				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
SINUS CONGESTION				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
SNEEZING				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
THROAT IRRITATION				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
UPPER RESPIRATORY TRACT CONGESTION				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
UPPER-AIRWAY COUGH SYNDROME				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		

WHEEZING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
ABNORMAL DREAMS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
AFFECT LABILITY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
ANXIETY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
APATHY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
CONFUSIONAL STATE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
DEPRESSED MOOD			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
DEPRESSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
EMOTIONAL DISORDER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
INSOMNIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
IRRITABILITY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
LIBIDO INCREASED			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
MANIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
MOOD SWINGS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
NIGHTMARE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
RESTLESSNESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
BLOOD BICARBONATE DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
BLOOD GLUCOSE INCREASED			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
BLOOD POTASSIUM INCREASED				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
BLOOD PRESSURE INCREASED				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
BLOOD TRIGLYCERIDES INCREASED				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
BLOOD UREA INCREASED				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
BLOOD URINE PRESENT				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
CARDIAC MURMUR				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
CYTOMEGALOVIRUS TEST POSITIVE				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
GAMMA-GLUTAMYLTRANSFERASE INCREASED				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
HAEMATOCRIT DECREASED				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
HAEMOGLOBIN DECREASED				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
IMMUNOSUPPRESSANT DRUG LEVEL INCREASED				

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
VITAMIN D DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
WEIGHT DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
WEIGHT INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
ACCIDENT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
ARTHROPOD BITE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
ARTHROPOD STING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
CONTUSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
EXCORIATION			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
FALL				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
FEMORAL NECK FRACTURE				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
JOINT INJURY				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
LACERATION				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
MUSCLE STRAIN				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
OVERDOSE				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
POST-TRAUMATIC NECK SYNDROME				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
SCRATCH				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
SUNBURN				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
SUPERFICIAL INJURY OF EYE				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
TOOTH FRACTURE				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
TRAUMATIC FRACTURE				

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
PALPITATIONS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
BALANCE DISORDER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
CAROTID ARTERY STENOSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
DIZZINESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
DYSGEUSIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
HEADACHE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
HYPERSOMNIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
HYPOAESTHESIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
MEMORY IMPAIRMENT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
MIGRAINE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
ORTHOSTATIC INTOLERANCE			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
PARAESTHESIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
POOR QUALITY SLEEP			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
PRESYNCOPE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
SEIZURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
SINUS HEADACHE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
SYNCOPE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
TENSION HEADACHE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
TREMOR			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
TUNNEL VISION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
HAEMOLYTIC ANAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	

LEUKOPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
LYMPHOPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
EAR PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
VERTIGO			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
DIPLOPIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
DRY EYE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
EYE PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
EYE PRURITUS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
OCULAR DISCOMFORT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
OCULAR HYPERAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
VISION BLURRED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
VISUAL IMPAIRMENT			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
VITREOUS FLOATERS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
ABDOMINAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
ANAL PRURITUS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
ANORECTAL DISCOMFORT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
APHTHOUS ULCER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
BOWEL MOVEMENT IRREGULARITY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
CONSTIPATION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	

DENTAL CARIES				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
DIARRHOEA				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
DIVERTICULUM INTESTINAL				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
DRY MOUTH				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
DYSPEPSIA				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
DYSPHAGIA				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
EPIGASTRIC DISCOMFORT				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
FAECES DISCOLOURED				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
FLATULENCE				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
GASTROOESOPHAGEAL REFLUX DISEASE				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
GINGIVAL BLEEDING				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
HAEMORRHOIDS				

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
LIP DRY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
NAUSEA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
OESOPHAGEAL DILATATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
TOOTH IMPACTED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
TOOTHACHE			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
VOMITING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hepatobiliary disorders			
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
JAUNDICE			
subjects affected / exposed	0 / 3 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Skin and subcutaneous tissue disorders			
ACNE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
ALOPECIA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
DERMATITIS CONTACT				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
DRY SKIN				
subjects affected / exposed	0 / 3 (0.00%)	1 / 1 (100.00%)		
occurrences (all)	0	1		
ERYTHEMA				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
HAIR GROWTH ABNORMAL				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
HYPERHIDROSIS				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
PETECHIAE				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
PHOTOSENSITIVITY REACTION				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
PRURITUS				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
PRURITUS GENERALISED				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
PSORIASIS				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
RASH				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
RASH GENERALISED				

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
RASH MACULAR			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
RASH PAPULAR			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
RASH PRURITIC			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
SKIN EXFOLIATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
SKIN LESION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
SKIN TIGHTNESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
URTICARIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
ANURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
CHROMATURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
DYSURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	

POLLAKIURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
POLYURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
PROTEINURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
URINARY RETENTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
ARTHRITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
BACK PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
FLANK PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
GOUTY ARTHRITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
GROIN PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
LIMB DISCOMFORT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
MUSCLE FATIGUE			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
MUSCLE SPASMS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
MUSCLE TWITCHING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
MUSCULOSKELETAL DISCOMFORT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
MYALGIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
NECK PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
TENDONITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
ACARODERMATITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
CELLULITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
CYTOMEGALOVIRUS VIRAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	

FOLLICULITIS				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
FUNGAL INFECTION				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
GASTROENTERITIS				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
HERPES ZOSTER				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
HORDEOLUM				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
IMPETIGO				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
INFLUENZA				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
LOCALISED INFECTION				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
ORAL CANDIDIASIS				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
ORAL HERPES				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
OTITIS MEDIA				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
PHARYNGITIS				
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		

PHARYNGITIS STREPTOCOCCAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
SINUSITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
SKIN INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
TINEA CRURIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
TINEA PEDIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
TOOTH INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
DEHYDRATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
DIABETES MELLITUS			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
DIABETES MELLITUS INADEQUATE CONTROL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
GOUT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
HYPERKALAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
HYPERURICAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
HYPOKALAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
HYPONATRAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 February 2013	The primary purpose of this amendment was to clarify requirements for rescreening subjects; clarify management of calcineurin inhibitor medications; update inclusion (clarify contraceptives/pregnancy, liver biopsy timeframes) and exclusion criteria (prior history including pegylated interferon [pegIFN] therapy, liver disease, other organ transplant, dietary habits); and clarify study activities.
08 April 2013	The primary purpose of this amendment was to prohibit the use of hormonal contraceptives during study drug administration.
12 December 2013	The primary purpose of this amendment was to update the introduction to reflect current case studies and analyses of study data; increase enrollment to 70 subjects; add study arms and further define cohorts 1 and 2; allow enrollment of subjects with interferon (IFN)/ribavirin(RBV) treatment failure, non-cirrhotic subjects with fibrosis scores up to F3 by Metavir Scale (or equivalent score by another scoring system), and subjects with subgenotype 1b who are treatment-naïve or treatment responders; make related updates to the study plan and inclusion and exclusion criteria); update cyclosporine and tacrolimus recommendations based on pharmacokinetic data; clarify blood sample collection; and add hepatitis C virus (HCV) treatment history and response to treatment definitions and collection criteria.
03 October 2014	The primary purpose of this amendment was to increase enrollment to 145 subjects; add ten study arms (Arms D through M) and further define Cohorts 3, 4, 5, and 6; allow enrollment of subjects with compensated cirrhosis (Child-Pugh A) after liver transplant, subjects who are 3 – 6 months post liver transplant, subjects who are more than 6 and less than 12 months post liver transplant with HCV-related elevation of liver enzymes (alanine aminotransferase [ALT] and/or aspartate aminotransferase [AST]), and subjects with chronic HCV who are at least 12 months post renal transplant; and make related updates to the study plan, rescreening criteria, and inclusion and exclusion criteria.
08 December 2014	The primary purpose of this amendment was to increase enrollment to 175 subjects; remove Arms H and K and combine Arms F and I and Arms G and J into a single Cohort (Cohort 4); combine Cohorts 4 and 5 to allow enrollment of subjects ≥ 3 months post liver transplant; change Cohort 6 (Renal Transplant) to Cohort 5; remove language limiting enrollment of renal transplant recipients with a Metavir score of F3 to 5 subjects; and make related update to the study plan and inclusion and exclusion criteria.
13 July 2015	The primary purpose of this amendment was to increase enrollment to 195; add Cohort 6 (HCV genotype 4-infected subjects post liver transplant); and make related updates to the study and inclusion and exclusion criteria.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported