



Clinical trial results:

A Phase II, Randomized, Open-Label Clinical Trial to Study the Efficacy and Safety of the Combination Regimen of MK-5172 and MK-3682 with Either MK-8742 or MK-8408 in Subjects with Chronic HCV GT3, GT4, GT5, and GT6 Infection

Summary

EudraCT number	2014-003347-35
Trial protocol	DK GB DE IT
Global end of trial date	03 May 2017

Results information

Result version number	v1
This version publication date	13 May 2018
First version publication date	13 May 2018

Trial information

Trial identification

Sponsor protocol code	3682-012
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02332720
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme Corp.
Sponsor organisation address	2000 Galloping Hill Road, Kenilworth, NJ, United States, 07033
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.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	03 May 2017
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	03 May 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This is a randomized, three-part, parallel-group, open-label trial of grazoprevir 100 mg and uprifosbuvir 300 mg or 450 mg with either elbasvir 50 mg or ruzasvir 60 mg, and with or without ribavirin (RBV), in treatment-naïve (TN) or treatment-experienced (TE) cirrhotic (C) or non-cirrhotic (NC) participants infected with hepatitis C virus (HCV) genotype (GT) 3, GT4, GT5, or GT6. In Part A, study therapy will be administered as separate products, each taken once daily (q.d.) by mouth. In Part B, participants will take 2 uprifosbuvir + grazoprevir + ruzasvir fixed dose combination (FDC) tablets q.d. by mouth, with or without twice-daily (b.i.d.) RBV (200 mg capsules; weight-based dosing). Participants who relapse following completion of therapy in Part A will be offered the option of retreatment with 16 weeks of uprifosbuvir + grazoprevir + ruzasvir with RBV in Part C (data obtained from Part C will not be used in the analysis of outcome measures).

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research. The following additional measure(s) defined for this individual study was in place for the protection of trial subjects: an option for retreatment of subjects who do not achieve SVR12 for reasons other than HCV virologic breakthrough, rebound or early discontinuation of therapy in Part A or Part B.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 January 2015
Long term follow-up planned	Yes
Long term follow-up rationale	Scientific research
Long term follow-up duration	3 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 27
Country: Number of subjects enrolled	Australia: 43
Country: Number of subjects enrolled	Denmark: 39
Country: Number of subjects enrolled	France: 19
Country: Number of subjects enrolled	Germany: 26
Country: Number of subjects enrolled	Israel: 60
Country: Number of subjects enrolled	Italy: 23
Country: Number of subjects enrolled	New Zealand: 23
Country: Number of subjects enrolled	Switzerland: 23
Country: Number of subjects enrolled	United Kingdom: 31

Country: Number of subjects enrolled	United States: 99
Worldwide total number of subjects	413
EEA total number of subjects	138

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)	394
From 65 to 84 years	19
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No participants were randomized to the 'B21: GT5 NC TN MK-3682B (12 weeks)' arm.

Pre-assignment

Screening details:

Participants were enrolled into either Part A or Part B. Part A enrolled non-cirrhotic (NC), treatment-naïve (TN) participants with hepatitis C virus (HCV) genotype (GT) 3; Part B enrolled NC or cirrhotic (C), TN or treatment-experienced (TE) participants with HCV GT3, GT4, GT5 or GT6. Participants who relapsed in Part A were retreated in Part C.

Period 1

Period 1 title	Pre-treatment randomization
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	A1: GT3 NC TN Grazoprevir+Uprifosbuvir+Elbasvir (8 weeks)

Arm description:

Part A: HCV GT3-infected NC TN participants received grazoprevir (100 mg) + uprifosbuvir (300 mg) + elbasvir (50 mg) q.d. by mouth for 8 weeks.

Arm type	Experimental
Investigational medicinal product name	Grazoprevir
Investigational medicinal product code	
Other name	MK-5172
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part A: one grazoprevir 100 mg tablet taken q.d. by mouth.

Investigational medicinal product name	Elbasvir
Investigational medicinal product code	
Other name	MK-8742
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Part A: one elbasvir 50 mg tablet taken q.d. by mouth.

Investigational medicinal product name	Uprifosbuvir
Investigational medicinal product code	
Other name	MK-3682
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part A: two uprifosbuvir 150 mg (300 mg total daily dose) tablets taken q.d. by mouth.

Arm title	A2: GT3 NC TN Grazoprevir+Uprifosbuvir+Ruzasvir (8 weeks)
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Arm description:

Part A: HCV GT3-infected NC TN participants received grazoprevir (100 mg) + uprifosbuvir (300 mg) + ruzasvir (60 mg) q.d. by mouth for 8 weeks.

Arm type	Experimental
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Investigational medicinal product name	Grazoprevir
Investigational medicinal product code	
Other name	MK-5172
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Part A: one grazoprevir 100 mg tablet taken q.d. by mouth.	
Investigational medicinal product name	Ruzasvir
Investigational medicinal product code	
Other name	MK-8408
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Part A: six ruzasvir 10 mg (60 mg total daily dose) capsules taken q.d. by mouth.	
Investigational medicinal product name	Uprifosbuvir
Investigational medicinal product code	
Other name	MK-3682
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Part A: two uprifosbuvir 150 mg (300 mg total daily dose) tablets taken q.d. by mouth.	
Arm title	A3: GT3 NC TN Grazoprevir+Uprifosbuvir+Elbasvir (8 weeks)
Arm description:	
Part A: HCV GT3-infected NC TN participants received grazoprevir (100 mg) + uprifosbuvir (450 mg) + elbasvir (50 mg) q.d. by mouth for 8 weeks.	
Arm type	Experimental
Investigational medicinal product name	Grazoprevir
Investigational medicinal product code	
Other name	MK-5172
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Part A: one grazoprevir 100 mg tablet taken q.d. by mouth.	
Investigational medicinal product name	Uprifosbuvir
Investigational medicinal product code	
Other name	MK-3682
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Part A: three uprifosbuvir 150 mg (450 mg total daily dose) tablets taken q.d. by mouth.	
Investigational medicinal product name	Elbasvir
Investigational medicinal product code	
Other name	MK-8742
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
Part A: one elbasvir 50 mg tablet taken q.d. by mouth.	
Arm title	A4: GT3 NC TN Grazoprevir+Uprifosbuvir+Ruzasvir (8 weeks)
Arm description:	
Part A: HCV GT3-infected NC TN participants received grazoprevir 100 mg + uprifosbuvir 450 mg + ruzasvir 60 mg q.d. by mouth for 8 weeks.	
Arm type	Experimental

Investigational medicinal product name	Grazoprevir
Investigational medicinal product code	
Other name	MK-5172
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Part A: one grazoprevir 100 mg tablet taken q.d. by mouth.	
Investigational medicinal product name	Uprifosbuvir
Investigational medicinal product code	
Other name	MK-3682
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Part A: three uprifosbuvir 150 mg (450 mg total daily dose) tablets taken q.d. by mouth.	
Investigational medicinal product name	Ruzasvir
Investigational medicinal product code	
Other name	MK-8408
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Part A: six ruzasvir 10 mg (60 mg total daily dose) capsules taken q.d. by mouth.	
Investigational medicinal product name	Grazoprevir
Investigational medicinal product code	
Other name	MK-5172
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Part A: one grazoprevir 100 mg tablet taken q.d. by mouth.	
Investigational medicinal product name	Uprifosbuvir
Investigational medicinal product code	
Other name	MK-3682
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Part A: three uprifosbuvir 150 mg (450 mg total daily dose) tablets taken q.d. by mouth.	
Investigational medicinal product name	Ruzasvir
Investigational medicinal product code	
Other name	MK-8408
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Part A: six ruzasvir 10 mg (60 mg total daily dose) capsules taken q.d. by mouth.	
Arm title	B4: GT3 NC TN MK-3682B (8 weeks)
Arm description:	
Part B: HCV GT3-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 8 weeks.	
Arm type	Experimental

Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.	
Arm title	B5: GT3 NC TN MK-3682B + RBV (8 weeks)
Arm description:	
Part B: HCV GT3-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 8 weeks.	
Arm type	Experimental
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.	
Investigational medicinal product name	Ribavirin
Investigational medicinal product code	
Other name	Rebetol
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
Part B: RBV 200 mg capsules taken b.i.d. by mouth at a total daily dose of 800 mg - 1400 mg based on participant body weight.	
Arm title	B6: GT3 NC TN MK-3682B (12 weeks)
Arm description:	
Part B: HCV GT3-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.	
Arm type	Experimental
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.	
Arm title	B7: GT3 NC TN MK-3682B + RBV (12 weeks)
Arm description:	
Part B: HCV GT3-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 12 weeks.	
Arm type	Experimental

Investigational medicinal product name	Ribavirin
Investigational medicinal product code	
Other name	Rebetol
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
Part B: RBV 200 mg capsules taken b.i.d. by mouth at a total daily dose of 800 mg - 1400 mg based on participant body weight.	
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.	
Arm title	B8: GT3 NC TE MK-3682B (8 weeks)
Arm description:	
Part B: HCV GT3-infected NC TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 8 weeks.	
Arm type	Experimental
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.	
Arm title	B9: GT3 NC TE MK-3682B + RBV (8 weeks)
Arm description:	
Part B: HCV GT3-infected NC TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 8 weeks.	
Arm type	Experimental
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.	
Investigational medicinal product name	Ribavirin
Investigational medicinal product code	
Other name	Rebetol
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
Part B: RBV 200 mg capsules taken b.i.d. by mouth at a total daily dose of 800 mg - 1400 mg based on participant body weight.	
Arm title	B10: GT3 NC TE MK-3682B (12 weeks)

Arm description:

Part B: HCV GT3-infected NC TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.

Arm type	Experimental
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.

Arm title	B11: GT3 NC TE MK-3682B + RBV (12 weeks)
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Arm description:

Part B: HCV GT3-infected NC TE participants received 2 MK-3682 FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 12 weeks.

Arm type	Experimental
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.

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

Dosage and administration details:

Part B: RBV 200 mg capsules taken b.i.d. by mouth at a total daily dose of 800 mg - 1400 mg based on participant body weight.

Arm title	B12: GT3 NC TE MK-3682B (16 weeks)
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Arm description:

Part B: HCV GT3-infected NC TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 16 weeks.

Arm type	Experimental
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.

Arm title	B13: GT3 C TN MK-3682B (12 weeks)
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Arm description:

Part B: HCV GT3-infected C TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.

Arm type	Experimental
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Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.	
Arm title	B14: GT3 C TN MK-3682B + RBV (12 weeks)
Arm description:	
Part B: HCV GT3-infected C TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 12 weeks.	
Arm type	Experimental
Investigational medicinal product name	Ribavirin
Investigational medicinal product code	
Other name	Rebetol
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
Part B: RBV 200 mg capsules taken b.i.d. by mouth at a total daily dose of 800 mg - 1400 mg based on participant body weight.	
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.	
Arm title	B15: GT3 C TN MK-3682B (16 weeks)
Arm description:	
Part B: HCV GT3-infected C TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 16 weeks.	
Arm type	Experimental
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.	
Arm title	B16: GT3 C TE MK-3682B (12 weeks)
Arm description:	
Part B: HCV GT3-infected C TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.	
Arm type	Experimental
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.

Arm title	B17: GT3 C TE MK-3682B + RBV (12 weeks)
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Arm description:

Part B: HCV GT3-infected C TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 12 weeks.

Arm type	Experimental
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.

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

Dosage and administration details:

Part B: RBV 200 mg capsules taken b.i.d. by mouth at a total daily dose of 800 mg - 1400 mg based on participant body weight.

Arm title	B18: GT3 C TE MK-3682B (16 weeks)
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Arm description:

Part B: HCV GT3-infected C TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 16 weeks.

Arm type	Experimental
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.

Arm title	B19: GT3 C TE MK-3682B + RBV (16 weeks)
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Arm description:

Part B: HCV GT3-infected C TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 16 weeks.

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

Dosage and administration details:

Part B: RBV 200 mg capsules taken b.i.d. by mouth at a total daily dose of 800 mg - 1400 mg based on

participant body weight.

Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.

Arm title	B20: GT4 NC TN MK-3682B (8 weeks)
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Arm description:

Part B: HCV GT4-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 8 weeks.

Arm type	Experimental
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.

Arm title	B22: GT6 NC TN MK-3682B (12 weeks)
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Arm description:

Part B: HCV GT6-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.

Arm type	Experimental
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.

Number of subjects in period 1	A1: GT3 NC TN Grazoprevir+Uprifos buvir+Elbasvir (8 weeks)	A2: GT3 NC TN Grazoprevir+Uprifos buvir+Ruzasvir (8 weeks)	A3: GT3 NC TN Grazoprevir+Uprifos buvir+Elbasvir (8 weeks)
Started	21	21	22
Completed	21	21	22
Not completed	0	0	0
Physician decision	-	-	-

Number of subjects in period 1	A4: GT3 NC TN Grazoprevir+Uprifos buvir+Ruzasvir (8 weeks)	B4: GT3 NC TN MK- 3682B (8 weeks)	B5: GT3 NC TN MK- 3682B + RBV (8 weeks)
Started	22	16	36

Completed	22	16	36
Not completed	0	0	0
Physician decision	-	-	-

Number of subjects in period 1	B6: GT3 NC TN MK-3682B (12 weeks)	B7: GT3 NC TN MK-3682B + RBV (12 weeks)	B8: GT3 NC TE MK-3682B (8 weeks)
Started	37	35	15
Completed	37	35	15
Not completed	0	0	0
Physician decision	-	-	-

Number of subjects in period 1	B9: GT3 NC TE MK-3682B + RBV (8 weeks)	B10: GT3 NC TE MK-3682B (12 weeks)	B11: GT3 NC TE MK-3682B + RBV (12 weeks)
Started	14	14	15
Completed	14	14	15
Not completed	0	0	0
Physician decision	-	-	-

Number of subjects in period 1	B12: GT3 NC TE MK-3682B (16 weeks)	B13: GT3 C TN MK-3682B (12 weeks)	B14: GT3 C TN MK-3682B + RBV (12 weeks)
Started	16	13	16
Completed	16	13	16
Not completed	0	0	0
Physician decision	-	-	-

Number of subjects in period 1	B15: GT3 C TN MK-3682B (16 weeks)	B16: GT3 C TE MK-3682B (12 weeks)	B17: GT3 C TE MK-3682B + RBV (12 weeks)
Started	14	15	14
Completed	14	15	14
Not completed	0	0	0
Physician decision	-	-	-

Number of subjects in period 1	B18: GT3 C TE MK-3682B (16 weeks)	B19: GT3 C TE MK-3682B + RBV (16 weeks)	B20: GT4 NC TN MK-3682B (8 weeks)
Started	21	25	7
Completed	20	25	7
Not completed	1	0	0
Physician decision	1	-	-

Number of subjects in period 1	B22: GT6 NC TN MK-3682B (12 weeks)
Started	4
Completed	4
Not completed	0
Physician decision	-

Period 2	
Period 2 title	Part A and Part B Treatment Period
Is this the baseline period?	Yes ^[1]
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	A1: GT3 NC TN Grazoprevir+Uprifosbuvir+Elbasvir (8 weeks)

Arm description:

Part A: HCV GT3-infected NC TN participants received grazoprevir (100 mg) + uprifosbuvir (300 mg) + elbasvir (50 mg) q.d. by mouth for 8 weeks.

Arm type	Experimental
Investigational medicinal product name	Grazoprevir
Investigational medicinal product code	
Other name	MK-5172
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part A: one grazoprevir 100 mg tablet taken q.d. by mouth.

Investigational medicinal product name	Elbasvir
Investigational medicinal product code	
Other name	MK-8742
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Part A: one elbasvir 50 mg tablet taken q.d. by mouth.

Investigational medicinal product name	Uprifosbuvir
Investigational medicinal product code	
Other name	MK-3682
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part A: two uprifosbuvir 150 mg (300 mg total daily dose) tablets taken q.d. by mouth.

Arm title	A2: GT3 NC TN Grazoprevir+Uprifosbuvir+Ruzasvir (8 weeks)
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Arm description:

Part A: HCV GT3-infected NC TN participants received grazoprevir (100 mg) + uprifosbuvir (300 mg) + ruzasvir (60 mg) q.d. by mouth for 8 weeks.

Arm type	Experimental
Investigational medicinal product name	Grazoprevir
Investigational medicinal product code	
Other name	MK-5172
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part A: one grazoprevir 100 mg tablet taken q.d. by mouth.

Investigational medicinal product name	Ruzasvir
Investigational medicinal product code	
Other name	MK-8408
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Part A: six ruzasvir 10 mg (60 mg total daily dose) capsules taken q.d. by mouth.	
Investigational medicinal product name	Uprifosbuvir
Investigational medicinal product code	
Other name	MK-3682
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Part A: two uprifosbuvir 150 mg (300 mg total daily dose) tablets taken q.d. by mouth.	
Arm title	A3: GT3 NC TN Grazoprevir+Uprifosbuvir+Elbasvir (8 weeks)
Arm description:	
Part A: HCV GT3-infected NC TN participants received grazoprevir (100 mg) + uprifosbuvir (450 mg) + elbasvir (50 mg) q.d. by mouth for 8 weeks.	
Arm type	Experimental
Investigational medicinal product name	Grazoprevir
Investigational medicinal product code	
Other name	MK-5172
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Part A: one grazoprevir 100 mg tablet taken q.d. by mouth.	
Investigational medicinal product name	Uprifosbuvir
Investigational medicinal product code	
Other name	MK-3682
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Part A: three uprifosbuvir 150 mg (450 mg total daily dose) tablets taken q.d. by mouth.	
Investigational medicinal product name	Elbasvir
Investigational medicinal product code	
Other name	MK-8742
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
Part A: one elbasvir 50 mg tablet taken q.d. by mouth.	
Arm title	A4: GT3 NC TN Grazoprevir+Uprifosbuvir+Ruzasvir (8 weeks)
Arm description:	
Part A: HCV GT3-infected NC TN participants received grazoprevir 100 mg + uprifosbuvir 450 mg + ruzasvir 60 mg q.d. by mouth for 8 weeks.	
Arm type	Experimental
Investigational medicinal product name	Grazoprevir
Investigational medicinal product code	
Other name	MK-5172
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Part A: one grazoprevir 100 mg tablet taken q.d. by mouth.	

Investigational medicinal product name	Uprifosbuvir
Investigational medicinal product code	
Other name	MK-3682
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part A: three uprifosbuvir 150 mg (450 mg total daily dose) tablets taken q.d. by mouth.

Investigational medicinal product name	Ruzasvir
Investigational medicinal product code	
Other name	MK-8408
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part A: six ruzasvir 10 mg (60 mg total daily dose) capsules taken q.d. by mouth.

Investigational medicinal product name	Grazoprevir
Investigational medicinal product code	
Other name	MK-5172
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part A: one grazoprevir 100 mg tablet taken q.d. by mouth.

Investigational medicinal product name	Uprifosbuvir
Investigational medicinal product code	
Other name	MK-3682
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part A: three uprifosbuvir 150 mg (450 mg total daily dose) tablets taken q.d. by mouth.

Investigational medicinal product name	Ruzasvir
Investigational medicinal product code	
Other name	MK-8408
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part A: six ruzasvir 10 mg (60 mg total daily dose) capsules taken q.d. by mouth.

Arm title	B4: GT3 NC TN MK-3682B (8 weeks)
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Arm description:

Part B: HCV GT3-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 8 weeks.

Arm type	Experimental
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.

Arm title	B5: GT3 NC TN MK-3682B + RBV (8 weeks)
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Arm description:

Part B: HCV GT3-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d.,

by mouth for 8 weeks.

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

Dosage and administration details:

Part B: RBV 200 mg capsules taken b.i.d. by mouth at a total daily dose of 800 mg - 1400 mg based on participant body weight.

Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.

Arm title	B6: GT3 NC TN MK-3682B (12 weeks)
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Arm description:

Part B: HCV GT3-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.

Arm type	Experimental
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.

Arm title	B7: GT3 NC TN MK-3682B + RBV (12 weeks)
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Arm description:

Part B: HCV GT3-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 12 weeks.

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

Dosage and administration details:

Part B: RBV 200 mg capsules taken b.i.d. by mouth at a total daily dose of 800 mg - 1400 mg based on participant body weight.

Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.

Arm title	B8: GT3 NC TE MK-3682B (8 weeks)
Arm description: Part B: HCV GT3-infected NC TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 8 weeks.	
Arm type	Experimental
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.	
Arm title	B9: GT3 NC TE MK-3682B + RBV (8 weeks)
Arm description: Part B: HCV GT3-infected NC TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 8 weeks.	
Arm type	Experimental
Investigational medicinal product name	Ribavirin
Investigational medicinal product code	
Other name	Rebetol
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: Part B: RBV 200 mg capsules taken b.i.d. by mouth at a total daily dose of 800 mg - 1400 mg based on participant body weight.	
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.	
Arm title	B10: GT3 NC TE MK-3682B (12 weeks)
Arm description: Part B: HCV GT3-infected NC TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.	
Arm type	Experimental
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.	
Arm title	B11: GT3 NC TE MK-3682B + RBV (12 weeks)
Arm description: Part B: HCV GT3-infected NC TE participants received 2 MK-3682 FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 12 weeks.	
Arm type	Experimental

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

Dosage and administration details:

Part B: RBV 200 mg capsules taken b.i.d. by mouth at a total daily dose of 800 mg - 1400 mg based on participant body weight.

Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.

Arm title	B12: GT3 NC TE MK-3682B (16 weeks)
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Arm description:

Part B: HCV GT3-infected NC TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 16 weeks.

Arm type	Experimental
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.

Arm title	B13: GT3 C TN MK-3682B (12 weeks)
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Arm description:

Part B: HCV GT3-infected C TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.

Arm type	Experimental
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.

Arm title	B14: GT3 C TN MK-3682B + RBV (12 weeks)
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Arm description:

Part B: HCV GT3-infected C TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 12 weeks.

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

Dosage and administration details:

Part B: RBV 200 mg capsules taken b.i.d. by mouth at a total daily dose of 800 mg - 1400 mg based on participant body weight.

Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.

Arm title	B15: GT3 C TN MK-3682B (16 weeks)
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Arm description:

Part B: HCV GT3-infected C TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 16 weeks.

Arm type	Experimental
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.

Arm title	B16: GT3 C TE MK-3682B (12 weeks)
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Arm description:

Part B: HCV GT3-infected C TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.

Arm type	Experimental
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.

Arm title	B17: GT3 C TE MK-3682B + RBV (12 weeks)
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Arm description:

Part B: HCV GT3-infected C TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 12 weeks.

Arm type	Experimental
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.

Investigational medicinal product name	Ribavirin
Investigational medicinal product code	
Other name	Rebetol

Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Part B: RBV 200 mg capsules taken b.i.d. by mouth at a total daily dose of 800 mg - 1400 mg based on participant body weight.

Arm title	B18: GT3 C TE MK-3682B (16 weeks)
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Arm description:

Part B: HCV GT3-infected C TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 16 weeks.

Arm type	Experimental
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.

Arm title	B19: GT3 C TE MK-3682B + RBV (16 weeks)
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Arm description:

Part B: HCV GT3-infected C TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 16 weeks.

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

Dosage and administration details:

Part B: RBV 200 mg capsules taken b.i.d. by mouth at a total daily dose of 800 mg - 1400 mg based on participant body weight.

Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.

Arm title	B20: GT4 NC TN MK-3682B (8 weeks)
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Arm description:

Part B: HCV GT4-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 8 weeks.

Arm type	Experimental
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.

Arm title	B22: GT6 NC TN MK-3682B (12 weeks)
Arm description: Part B: HCV GT6-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.	
Arm type	Experimental
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.	
Notes: [1] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period. Justification: Baseline participants include participants who received at least one dose of study drug. One 'B18: GT3 C TE MK-3682B (16 weeks)' participant did not receive any study drug.	

Number of subjects in period 2^[2]	A1: GT3 NC TN Grazoprevir+Uprifosbuvir+Elbasvir (8 weeks)	A2: GT3 NC TN Grazoprevir+Uprifosbuvir+Ruzasvir (8 weeks)	A3: GT3 NC TN Grazoprevir+Uprifosbuvir+Elbasvir (8 weeks)
Started	21	21	22
Treated	21	21	22
Completed	20	21	22
Not completed	1	0	0
Consent withdrawn by subject	-	-	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	1	-	-

Number of subjects in period 2^[2]	A4: GT3 NC TN Grazoprevir+Uprifosbuvir+Ruzasvir (8 weeks)	B4: GT3 NC TN MK-3682B (8 weeks)	B5: GT3 NC TN MK-3682B + RBV (8 weeks)
Started	22	16	36
Treated	22	16	36
Completed	22	16	33
Not completed	0	0	3
Consent withdrawn by subject	-	-	1
Adverse event, non-fatal	-	-	-
Lost to follow-up	-	-	2

Number of subjects in period 2^[2]	B6: GT3 NC TN MK-3682B (12 weeks)	B7: GT3 NC TN MK-3682B + RBV (12 weeks)	B8: GT3 NC TE MK-3682B (8 weeks)
Started	37	35	15
Treated	37	35	15
Completed	36	34	15
Not completed	1	1	0
Consent withdrawn by subject	-	-	-
Adverse event, non-fatal	-	-	-

Lost to follow-up	1	1	-
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Number of subjects in period 2 ^[2]	B9: GT3 NC TE MK-3682B + RBV (8 weeks)	B10: GT3 NC TE MK-3682B (12 weeks)	B11: GT3 NC TE MK-3682B + RBV (12 weeks)
Started	14	14	15
Treated	14	14	15
Completed	14	14	15
Not completed	0	0	0
Consent withdrawn by subject	-	-	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 2 ^[2]	B12: GT3 NC TE MK-3682B (16 weeks)	B13: GT3 C TN MK-3682B (12 weeks)	B14: GT3 C TN MK-3682B + RBV (12 weeks)
Started	16	13	16
Treated	16	13	16
Completed	16	13	16
Not completed	0	0	0
Consent withdrawn by subject	-	-	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 2 ^[2]	B15: GT3 C TN MK-3682B (16 weeks)	B16: GT3 C TE MK-3682B (12 weeks)	B17: GT3 C TE MK-3682B + RBV (12 weeks)
Started	14	15	14
Treated	14	15	14
Completed	13	15	13
Not completed	1	0	1
Consent withdrawn by subject	-	-	-
Adverse event, non-fatal	-	-	1
Lost to follow-up	1	-	-

Number of subjects in period 2 ^[2]	B18: GT3 C TE MK-3682B (16 weeks)	B19: GT3 C TE MK-3682B + RBV (16 weeks)	B20: GT4 NC TN MK-3682B (8 weeks)
Started	20	25	7
Treated	20	25	7
Completed	20	24	7
Not completed	0	1	0
Consent withdrawn by subject	-	1	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 2 ^[2]	B22: GT6 NC TN MK-3682B (12 weeks)
Started	4

Treated	4
Completed	4
Not completed	0
Consent withdrawn by subject	-
Adverse event, non-fatal	-
Lost to follow-up	-

Notes:

[2] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: One participant randomized to the 'B18: GT3 C TE MK-3682B (16 weeks)' arm did not receive any study drug.

Period 3

Period 3 title	Part C Treatment Period
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	A1: GT3 NC TN Grazoprevir+Uprifosbuvir+Elbasvir (8 weeks)

Arm description:

Part C: Part A participants who relapsed following completion of therapy were offered the option of retreatment with 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. and RBV (weight-based dosing) b.i.d. by mouth for 16 weeks.

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

Dosage and administration details:

Part C: RBV 200 mg capsules taken b.i.d. by mouth at a total daily dose of 800 mg - 1400 mg based on participant body weight.

Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part C: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.

Arm title	A2: GT3 NC TN Grazoprevir+Uprifosbuvir+Ruzasvir (8 weeks)
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Arm description:

Part C: Part A participants who relapsed following completion of therapy were offered the option of retreatment with 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. and RBV (weight-based dosing) b.i.d. by mouth for 16 weeks.

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

Dosage and administration details:

Part C: RBV 200 mg capsules taken b.i.d. by mouth at a total daily dose of 800 mg - 1400 mg based on participant body weight.

Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part C: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.

Arm title	A3: GT3 NC TN Grazoprevir+Uprifosbuvir+Elbasvir (8 weeks)
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Arm description:

Part C: Part A participants who relapsed following completion of therapy were offered the option of retreatment with 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. and RBV (weight-based dosing) b.i.d. by mouth for 16 weeks during Part C.

Arm type	Experimental
Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part C: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth.

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

Dosage and administration details:

Part C: RBV 200 mg capsules taken b.i.d. by mouth at a total daily dose of 800 mg - 1400 mg based on participant body weight.

Arm title	A4: GT3 NC TN Grazoprevir+Uprifosbuvir+Ruzasvir (8 weeks)
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Arm description:

Part C: Part A participants who relapsed following completion of therapy received retreatment with 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. and RBV (weight-based dosing) b.i.d. by mouth for 16 weeks during Part C.

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

Dosage and administration details:

Part C: RBV 200 mg capsules taken b.i.d. by mouth at a total daily dose of 800 mg - 1400 mg based on participant body weight.

Investigational medicinal product name	MK-3682B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Part C: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken

q.d. by mouth.

Number of subjects in period 3^[3]	A1: GT3 NC TN Grazoprevir+Uprifos buvir+Elbasvir (8 weeks)	A2: GT3 NC TN Grazoprevir+Uprifos buvir+Ruzasvir (8 weeks)	A3: GT3 NC TN Grazoprevir+Uprifos buvir+Elbasvir (8 weeks)
Started	2	1	3
Completed	2	1	3

Number of subjects in period 3^[3]	A4: GT3 NC TN Grazoprevir+Uprifos buvir+Ruzasvir (8 weeks)
Started	2
Completed	2

Notes:

[3] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Part A participants who relapsed following completion of therapy were offered the option of retreatment with 2 MK-3682B FDC tablets q.d. and RBV b.i.d. by mouth for 16 weeks.

Baseline characteristics

Reporting groups

Reporting group title	A1: GT3 NC TN Grazoprevir+Uprifosbuvir+Elbasvir (8 weeks)
Reporting group description: Part A: HCV GT3-infected NC TN participants received grazoprevir (100 mg) + uprifosbuvir (300 mg) + elbasvir (50 mg) q.d. by mouth for 8 weeks.	
Reporting group title	A2: GT3 NC TN Grazoprevir+Uprifosbuvir+Ruzasvir (8 weeks)
Reporting group description: Part A: HCV GT3-infected NC TN participants received grazoprevir (100 mg) + uprifosbuvir (300 mg) + ruzasvir (60 mg) q.d. by mouth for 8 weeks.	
Reporting group title	A3: GT3 NC TN Grazoprevir+Uprifosbuvir+Elbasvir (8 weeks)
Reporting group description: Part A: HCV GT3-infected NC TN participants received grazoprevir (100 mg) + uprifosbuvir (450 mg) + elbasvir (50 mg) q.d. by mouth for 8 weeks.	
Reporting group title	A4: GT3 NC TN Grazoprevir+Uprifosbuvir+Ruzasvir (8 weeks)
Reporting group description: Part A: HCV GT3-infected NC TN participants received grazoprevir 100 mg + uprifosbuvir 450 mg + ruzasvir 60 mg q.d. by mouth for 8 weeks.	
Reporting group title	B4: GT3 NC TN MK-3682B (8 weeks)
Reporting group description: Part B: HCV GT3-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 8 weeks.	
Reporting group title	B5: GT3 NC TN MK-3682B + RBV (8 weeks)
Reporting group description: Part B: HCV GT3-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 8 weeks.	
Reporting group title	B6: GT3 NC TN MK-3682B (12 weeks)
Reporting group description: Part B: HCV GT3-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.	
Reporting group title	B7: GT3 NC TN MK-3682B + RBV (12 weeks)
Reporting group description: Part B: HCV GT3-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 12 weeks.	
Reporting group title	B8: GT3 NC TE MK-3682B (8 weeks)
Reporting group description: Part B: HCV GT3-infected NC TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 8 weeks.	
Reporting group title	B9: GT3 NC TE MK-3682B + RBV (8 weeks)
Reporting group description: Part B: HCV GT3-infected NC TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 8 weeks.	
Reporting group title	B10: GT3 NC TE MK-3682B (12 weeks)
Reporting group description: Part B: HCV GT3-infected NC TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.	
Reporting group title	B11: GT3 NC TE MK-3682B + RBV (12 weeks)
Reporting group description: Part B: HCV GT3-infected NC TE participants received 2 MK-3682 FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 12 weeks.	
Reporting group title	B12: GT3 NC TE MK-3682B (16 weeks)

Reporting group description:

Part B: HCV GT3-infected NC TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 16 weeks.

Reporting group title	B13: GT3 C TN MK-3682B (12 weeks)
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Reporting group description:

Part B: HCV GT3-infected C TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.

Reporting group title	B14: GT3 C TN MK-3682B + RBV (12 weeks)
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Reporting group description:

Part B: HCV GT3-infected C TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 12 weeks.

Reporting group title	B15: GT3 C TN MK-3682B (16 weeks)
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Reporting group description:

Part B: HCV GT3-infected C TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 16 weeks.

Reporting group title	B16: GT3 C TE MK-3682B (12 weeks)
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Reporting group description:

Part B: HCV GT3-infected C TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.

Reporting group title	B17: GT3 C TE MK-3682B + RBV (12 weeks)
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Reporting group description:

Part B: HCV GT3-infected C TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 12 weeks.

Reporting group title	B18: GT3 C TE MK-3682B (16 weeks)
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Reporting group description:

Part B: HCV GT3-infected C TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 16 weeks.

Reporting group title	B19: GT3 C TE MK-3682B + RBV (16 weeks)
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Reporting group description:

Part B: HCV GT3-infected C TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 16 weeks.

Reporting group title	B20: GT4 NC TN MK-3682B (8 weeks)
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Reporting group description:

Part B: HCV GT4-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 8 weeks.

Reporting group title	B22: GT6 NC TN MK-3682B (12 weeks)
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Reporting group description:

Part B: HCV GT6-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.

Reporting group values	A1: GT3 NC TN Grazoprevir+Uprifos buvir+Elbasvir (8 weeks)	A2: GT3 NC TN Grazoprevir+Uprifos buvir+Ruzasvir (8 weeks)	A3: GT3 NC TN Grazoprevir+Uprifos buvir+Elbasvir (8 weeks)
Number of subjects	21	21	22
Age, Customized Units: Subjects			
18 to 35 years	4	4	3
36 to 50 years	12	9	14
51 to 64 years	5	8	5
Over 64 years	0	0	0

Sex: Female, Male			
Units: Subjects			
Female	9	15	14
Male	12	6	8

Reporting group values	A4: GT3 NC TN Grazoprevir+Uprifos buvir+Ruzasvir (8 weeks)	B4: GT3 NC TN MK- 3682B (8 weeks)	B5: GT3 NC TN MK- 3682B + RBV (8 weeks)
Number of subjects	22	16	36
Age, Customized			
Units: Subjects			
18 to 35 years	4	3	8
36 to 50 years	12	4	11
51 to 64 years	3	6	16
Over 64 years	3	3	1
Sex: Female, Male			
Units: Subjects			
Female	11	7	19
Male	11	9	17

Reporting group values	B6: GT3 NC TN MK- 3682B (12 weeks)	B7: GT3 NC TN MK- 3682B + RBV (12 weeks)	B8: GT3 NC TE MK- 3682B (8 weeks)
Number of subjects	37	35	15
Age, Customized			
Units: Subjects			
18 to 35 years	9	7	0
36 to 50 years	14	12	5
51 to 64 years	13	16	8
Over 64 years	1	0	2
Sex: Female, Male			
Units: Subjects			
Female	23	23	7
Male	14	12	8

Reporting group values	B9: GT3 NC TE MK- 3682B + RBV (8 weeks)	B10: GT3 NC TE MK- 3682B (12 weeks)	B11: GT3 NC TE MK- 3682B + RBV (12 weeks)
Number of subjects	14	14	15
Age, Customized			
Units: Subjects			
18 to 35 years	1	2	1
36 to 50 years	5	6	4
51 to 64 years	7	6	9
Over 64 years	1	0	1
Sex: Female, Male			
Units: Subjects			
Female	2	8	6
Male	12	6	9

Reporting group values	B12: GT3 NC TE MK- 3682B (16 weeks)	B13: GT3 C TN MK- 3682B (12 weeks)	B14: GT3 C TN MK- 3682B + RBV (12 weeks)
Number of subjects	16	13	16

Age, Customized			
Units: Subjects			
18 to 35 years	0	0	0
36 to 50 years	6	7	3
51 to 64 years	9	4	13
Over 64 years	1	2	0
Sex: Female, Male			
Units: Subjects			
Female	5	3	5
Male	11	10	11

Reporting group values	B15: GT3 C TN MK-3682B (16 weeks)	B16: GT3 C TE MK-3682B (12 weeks)	B17: GT3 C TE MK-3682B + RBV (12 weeks)
Number of subjects	14	15	14
Age, Customized			
Units: Subjects			
18 to 35 years	0	0	2
36 to 50 years	3	4	3
51 to 64 years	9	11	9
Over 64 years	2	0	0
Sex: Female, Male			
Units: Subjects			
Female	3	8	1
Male	11	7	13

Reporting group values	B18: GT3 C TE MK-3682B (16 weeks)	B19: GT3 C TE MK-3682B + RBV (16 weeks)	B20: GT4 NC TN MK-3682B (8 weeks)
Number of subjects	20	25	7
Age, Customized			
Units: Subjects			
18 to 35 years	0	0	1
36 to 50 years	6	6	3
51 to 64 years	13	18	3
Over 64 years	1	1	0
Sex: Female, Male			
Units: Subjects			
Female	2	5	1
Male	18	20	6

Reporting group values	B22: GT6 NC TN MK-3682B (12 weeks)	Total	
Number of subjects	4	412	
Age, Customized			
Units: Subjects			
18 to 35 years	0	49	
36 to 50 years	1	150	
51 to 64 years	3	194	
Over 64 years	0	19	
Sex: Female, Male			
Units: Subjects			
Female	2	179	

Male	2	233	
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End points

End points reporting groups

Reporting group title	A1: GT3 NC TN Grazoprevir+Uprifosbuvir+Elbasvir (8 weeks)
Reporting group description: Part A: HCV GT3-infected NC TN participants received grazoprevir (100 mg) + uprifosbuvir (300 mg) + elbasvir (50 mg) q.d. by mouth for 8 weeks.	
Reporting group title	A2: GT3 NC TN Grazoprevir+Uprifosbuvir+Ruzasvir (8 weeks)
Reporting group description: Part A: HCV GT3-infected NC TN participants received grazoprevir (100 mg) + uprifosbuvir (300 mg) + ruzasvir (60 mg) q.d. by mouth for 8 weeks.	
Reporting group title	A3: GT3 NC TN Grazoprevir+Uprifosbuvir+Elbasvir (8 weeks)
Reporting group description: Part A: HCV GT3-infected NC TN participants received grazoprevir (100 mg) + uprifosbuvir (450 mg) + elbasvir (50 mg) q.d. by mouth for 8 weeks.	
Reporting group title	A4: GT3 NC TN Grazoprevir+Uprifosbuvir+Ruzasvir (8 weeks)
Reporting group description: Part A: HCV GT3-infected NC TN participants received grazoprevir 100 mg + uprifosbuvir 450 mg + ruzasvir 60 mg q.d. by mouth for 8 weeks.	
Reporting group title	B4: GT3 NC TN MK-3682B (8 weeks)
Reporting group description: Part B: HCV GT3-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 8 weeks.	
Reporting group title	B5: GT3 NC TN MK-3682B + RBV (8 weeks)
Reporting group description: Part B: HCV GT3-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 8 weeks.	
Reporting group title	B6: GT3 NC TN MK-3682B (12 weeks)
Reporting group description: Part B: HCV GT3-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.	
Reporting group title	B7: GT3 NC TN MK-3682B + RBV (12 weeks)
Reporting group description: Part B: HCV GT3-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 12 weeks.	
Reporting group title	B8: GT3 NC TE MK-3682B (8 weeks)
Reporting group description: Part B: HCV GT3-infected NC TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 8 weeks.	
Reporting group title	B9: GT3 NC TE MK-3682B + RBV (8 weeks)
Reporting group description: Part B: HCV GT3-infected NC TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 8 weeks.	
Reporting group title	B10: GT3 NC TE MK-3682B (12 weeks)
Reporting group description: Part B: HCV GT3-infected NC TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.	
Reporting group title	B11: GT3 NC TE MK-3682B + RBV (12 weeks)
Reporting group description: Part B: HCV GT3-infected NC TE participants received 2 MK-3682 FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 12 weeks.	

Reporting group title	B12: GT3 NC TE MK-3682B (16 weeks)
Reporting group description: Part B: HCV GT3-infected NC TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 16 weeks.	
Reporting group title	B13: GT3 C TN MK-3682B (12 weeks)
Reporting group description: Part B: HCV GT3-infected C TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.	
Reporting group title	B14: GT3 C TN MK-3682B + RBV (12 weeks)
Reporting group description: Part B: HCV GT3-infected C TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 12 weeks.	
Reporting group title	B15: GT3 C TN MK-3682B (16 weeks)
Reporting group description: Part B: HCV GT3-infected C TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 16 weeks.	
Reporting group title	B16: GT3 C TE MK-3682B (12 weeks)
Reporting group description: Part B: HCV GT3-infected C TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.	
Reporting group title	B17: GT3 C TE MK-3682B + RBV (12 weeks)
Reporting group description: Part B: HCV GT3-infected C TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 12 weeks.	
Reporting group title	B18: GT3 C TE MK-3682B (16 weeks)
Reporting group description: Part B: HCV GT3-infected C TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 16 weeks.	
Reporting group title	B19: GT3 C TE MK-3682B + RBV (16 weeks)
Reporting group description: Part B: HCV GT3-infected C TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 16 weeks.	
Reporting group title	B20: GT4 NC TN MK-3682B (8 weeks)
Reporting group description: Part B: HCV GT4-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 8 weeks.	
Reporting group title	B22: GT6 NC TN MK-3682B (12 weeks)
Reporting group description: Part B: HCV GT6-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.	
Reporting group title	A1: GT3 NC TN Grazoprevir+Uprifosbuvir+Elbasvir (8 weeks)
Reporting group description: Part A: HCV GT3-infected NC TN participants received grazoprevir (100 mg) + uprifosbuvir (300 mg) + elbasvir (50 mg) q.d. by mouth for 8 weeks.	
Reporting group title	A2: GT3 NC TN Grazoprevir+Uprifosbuvir+Ruzasvir (8 weeks)
Reporting group description: Part A: HCV GT3-infected NC TN participants received grazoprevir (100 mg) + uprifosbuvir (300 mg) + ruzasvir (60 mg) q.d. by mouth for 8 weeks.	
Reporting group title	A3: GT3 NC TN Grazoprevir+Uprifosbuvir+Elbasvir (8 weeks)
Reporting group description: Part A: HCV GT3-infected NC TN participants received grazoprevir (100 mg) + uprifosbuvir (450 mg) + elbasvir (50 mg) q.d. by mouth for 8 weeks.	
Reporting group title	A4: GT3 NC TN Grazoprevir+Uprifosbuvir+Ruzasvir (8 weeks)

Reporting group description:

Part A: HCV GT3-infected NC TN participants received grazoprevir 100 mg + uprifosbuvir 450 mg + ruzasvir 60 mg q.d. by mouth for 8 weeks.

Reporting group title	B4: GT3 NC TN MK-3682B (8 weeks)
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Reporting group description:

Part B: HCV GT3-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 8 weeks.

Reporting group title	B5: GT3 NC TN MK-3682B + RBV (8 weeks)
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Reporting group description:

Part B: HCV GT3-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 8 weeks.

Reporting group title	B6: GT3 NC TN MK-3682B (12 weeks)
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Reporting group description:

Part B: HCV GT3-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.

Reporting group title	B7: GT3 NC TN MK-3682B + RBV (12 weeks)
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Reporting group description:

Part B: HCV GT3-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 12 weeks.

Reporting group title	B8: GT3 NC TE MK-3682B (8 weeks)
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Reporting group description:

Part B: HCV GT3-infected NC TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 8 weeks.

Reporting group title	B9: GT3 NC TE MK-3682B + RBV (8 weeks)
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Reporting group description:

Part B: HCV GT3-infected NC TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 8 weeks.

Reporting group title	B10: GT3 NC TE MK-3682B (12 weeks)
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Reporting group description:

Part B: HCV GT3-infected NC TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.

Reporting group title	B11: GT3 NC TE MK-3682B + RBV (12 weeks)
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Reporting group description:

Part B: HCV GT3-infected NC TE participants received 2 MK-3682 FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 12 weeks.

Reporting group title	B12: GT3 NC TE MK-3682B (16 weeks)
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Reporting group description:

Part B: HCV GT3-infected NC TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 16 weeks.

Reporting group title	B13: GT3 C TN MK-3682B (12 weeks)
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Reporting group description:

Part B: HCV GT3-infected C TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.

Reporting group title	B14: GT3 C TN MK-3682B + RBV (12 weeks)
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Reporting group description:

Part B: HCV GT3-infected C TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 12 weeks.

Reporting group title	B15: GT3 C TN MK-3682B (16 weeks)
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Reporting group description:

Part B: HCV GT3-infected C TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 16 weeks.

Reporting group title	B16: GT3 C TE MK-3682B (12 weeks)
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Reporting group description:

Part B: HCV GT3-infected C TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.

Reporting group title	B17: GT3 C TE MK-3682B + RBV (12 weeks)
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Reporting group description:

Part B: HCV GT3-infected C TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 12 weeks.

Reporting group title	B18: GT3 C TE MK-3682B (16 weeks)
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Reporting group description:

Part B: HCV GT3-infected C TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 16 weeks.

Reporting group title	B19: GT3 C TE MK-3682B + RBV (16 weeks)
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Reporting group description:

Part B: HCV GT3-infected C TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 16 weeks.

Reporting group title	B20: GT4 NC TN MK-3682B (8 weeks)
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Reporting group description:

Part B: HCV GT4-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 8 weeks.

Reporting group title	B22: GT6 NC TN MK-3682B (12 weeks)
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Reporting group description:

Part B: HCV GT6-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.

Reporting group title	A1: GT3 NC TN Grazoprevir+Uprifosbuvir+Elbasvir (8 weeks)
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Reporting group description:

Part C: Part A participants who relapsed following completion of therapy were offered the option of retreatment with 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. and RBV (weight-based dosing) b.i.d. by mouth for 16 weeks.

Reporting group title	A2: GT3 NC TN Grazoprevir+Uprifosbuvir+Ruzasvir (8 weeks)
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Reporting group description:

Part C: Part A participants who relapsed following completion of therapy were offered the option of retreatment with 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. and RBV (weight-based dosing) b.i.d. by mouth for 16 weeks.

Reporting group title	A3: GT3 NC TN Grazoprevir+Uprifosbuvir+Elbasvir (8 weeks)
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Reporting group description:

Part C: Part A participants who relapsed following completion of therapy were offered the option of retreatment with 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. and RBV (weight-based dosing) b.i.d. by mouth for 16 weeks during Part C.

Reporting group title	A4: GT3 NC TN Grazoprevir+Uprifosbuvir+Ruzasvir (8 weeks)
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Reporting group description:

Part C: Part A participants who relapsed following completion of therapy received retreatment with 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. and RBV (weight-based dosing) b.i.d. by mouth for 16 weeks during Part C.

Subject analysis set title	A4+B4: GT3 NC TN MK-3682B (8 weeks)
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

HCV GT3-infected NC TN participants received grazoprevir 100 mg + uprifosbuvir 450 mg + ruzasvir 60 mg q.d. by mouth for 8 weeks during Part A or 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 8 weeks during Part B.

Subject analysis set title	A4+ B4: GT3 NC TN MK-3682B (8 weeks)
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

HCV GT3-infected NC TN participants received grazoprevir 100 mg + uprifosbuvir 450 mg + ruzasvir 60 mg q.d. by mouth for 8 weeks during Part A or 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 8 weeks during Part B.

Subject analysis set title	A4+B4: GT3 NC TN MK-3682B (8 weeks)
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Subject analysis set type	Sub-group analysis
Subject analysis set description: In Part B, HCV GT3-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 8 weeks.	
Subject analysis set title	Part C: GT3 NC TN: MK-3682B + RBV (16 weeks)
Subject analysis set type	Sub-group analysis
Subject analysis set description: Part A participants who relapsed following completion of therapy were offered the option of retreatment with 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. and RBV (weight-based dosing) b.i.d. by mouth for 16 weeks during Part C.	

Primary: Percentage of HCV GT3-infected participants achieving Sustained Virologic Response at follow-up Week 12 (SVR12)

End point title	Percentage of HCV GT3-infected participants achieving Sustained Virologic Response at follow-up Week 12 (SVR12) ^{[1][2]}
End point description: SVR12 is defined as HCV ribonucleic acid (RNA) less than the lower limit of quantification (<LLOQ, 15 IU/mL) 12 weeks after the end of all study therapy. A4+B4: GT3 NC TN MK-3682B (8 weeks) arm includes both participants from Part A and Part B who received equivalent dose of MK-3682B. Analysis population included HCV GT3 participants who received treatment and did not have major protocol deviations that may substantially affect the results of the SVR endpoints. Therefore, only GT3 treatment arms are presented in the table below.	
End point type	Primary
End point timeframe: Up to 20 weeks (Part A), up to 28 weeks (Part B)	
Notes: [1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. Justification: No statistical analyses were planned for this endpoint. [2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Analysis population consists of HCV GT3 participants who received treatment and did not have major protocol deviations that may substantially affect the results of the SVR endpoints.	

End point values	A1: GT3 NC TN Grazoprevir+U prifosbuvir+Elb asvir (8 weeks)	A2: GT3 NC TN Grazoprevir+U prifosbuvir+Ru zasvir (8 weeks)	A3: GT3 NC TN Grazoprevir+U prifosbuvir+Elb asvir (8 weeks)	A4: GT3 NC TN Grazoprevir+U prifosbuvir+Ru zasvir (8 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	21	22	22
Units: Percentage of participants				
number (confidence interval 95%)	90.5 (69.6 to 98.8)	95.2 (76.2 to 99.9)	86.4 (65.1 to 97.1)	90.9 (70.8 to 98.9)

End point values	B4: GT3 NC TN MK-3682B (8 weeks)	B5: GT3 NC TN MK-3682B + RBV (8 weeks)	B6: GT3 NC TN MK-3682B (12 weeks)	B7: GT3 NC TN MK-3682B + RBV (12 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	35	36	35
Units: Percentage of participants				
number (confidence interval 95%)	93.8 (69.8 to 99.8)	100.0 (90.0 to 100.0)	97.2 (85.5 to 99.9)	100.0 (90.0 to 100.0)

End point values	B8: GT3 NC TE MK-3682B (8 weeks)	B9: GT3 NC TE MK-3682B + RBV (8 weeks)	B10: GT3 NC TE MK-3682B (12 weeks)	B11: GT3 NC TE MK-3682B + RBV (12 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	14	14	15
Units: Percentage of participants				
number (confidence interval 95%)	100.0 (78.2 to 100.0)	92.9 (66.4 to 99.8)	100.0 (76.8 to 100.0)	93.3 (68.1 to 99.8)

End point values	B12: GT3 NC TE MK-3682B (16 weeks)	B13: GT3 C TN MK-3682B (12 weeks)	B14: GT3 C TN MK-3682B + RBV (12 weeks)	B15: GT3 C TN MK-3682B (16 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	13	16	13
Units: Percentage of participants				
number (confidence interval 95%)	93.8 (69.8 to 99.8)	92.3 (64.0 to 99.8)	100.0 (79.4 to 100.0)	100.0 (78.2 to 100.0)

End point values	B16: GT3 C TE MK-3682B (12 weeks)	B17: GT3 C TE MK-3682B + RBV (12 weeks)	B18: GT3 C TE MK-3682B (16 weeks)	B19: GT3 C TE MK-3682B + RBV (16 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	14	20	25
Units: Percentage of participants				
number (confidence interval 95%)	100.0 (78.2 to 100.0)	100.0 (76.8 to 100.0)	100.0 (83.2 to 100.0)	96.0 (79.6 to 99.9)

End point values	A4+B4: GT3 NC TN MK-3682B (8 weeks)			
Subject group type	Subject analysis set			
Number of subjects analysed	38			
Units: Percentage of participants				
number (confidence interval 95%)	92.1 (78.6 to 98.3)			

Statistical analyses

Primary: Number of participants experiencing an adverse event (AE)

End point title	Number of participants experiencing an adverse event (AE) ^[3]
End point description:	
An adverse event is defined as any untoward medical occurrence in a patient or clinical investigation participant administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment. Analysis population included all participants who received at least 1 dose of study drug, categorized according to the treatment actually received. A4+B4: GT3 NC TN MK-3682B (8 weeks) arm includes both participants from Part A and Part B who received equivalent dose of MK-3682B.	
End point type	Primary
End point timeframe:	
Up to 40 weeks	

Notes:

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

Justification: No statistical analyses were planned for this endpoint.

End point values	A1: GT3 NC TN Grazoprevir+U prifosbuvir+Elb asvir (8 weeks)	A2: GT3 NC TN Grazoprevir+U prifosbuvir+Ru zasvir (8 weeks)	A3: GT3 NC TN Grazoprevir+U prifosbuvir+Elb asvir (8 weeks)	A4: GT3 NC TN Grazoprevir+U prifosbuvir+Ru zasvir (8 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	21	22	22
Units: Participants	18	14	16	17

End point values	B4: GT3 NC TN MK-3682B (8 weeks)	B5: GT3 NC TN MK-3682B + RBV (8 weeks)	B6: GT3 NC TN MK-3682B (12 weeks)	B7: GT3 NC TN MK-3682B + RBV (12 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	36	37	35
Units: Participants	9	30	25	33

End point values	B8: GT3 NC TE MK-3682B (8 weeks)	B9: GT3 NC TE MK-3682B + RBV (8 weeks)	B10: GT3 NC TE MK-3682B (12 weeks)	B11: GT3 NC TE MK-3682B + RBV (12 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	14	14	15
Units: Participants	12	12	9	13

End point values	B12: GT3 NC TE MK-3682B (16 weeks)	B13: GT3 C TN MK-3682B (12 weeks)	B14: GT3 C TN MK-3682B + RBV (12 weeks)	B15: GT3 C TN MK-3682B (16 weeks)
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	13	16	14
Units: Participants	13	9	14	12

End point values	B16: GT3 C TE MK-3682B (12 weeks)	B17: GT3 C TE MK-3682B + RBV (12 weeks)	B18: GT3 C TE MK-3682B (16 weeks)	B19: GT3 C TE MK-3682B + RBV (16 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	14	20	25
Units: Participants	12	12	16	21

End point values	B20: GT4 NC TN MK-3682B (8 weeks)	B22: GT6 NC TN MK-3682B (12 weeks)	A4+B4: GT3 NC TN MK-3682B (8 weeks)	Part C: GT3 NC TN: MK-3682B + RBV (16 weeks)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	7	4	38	8
Units: Participants	3	3	26	7

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants who had study drug discontinued due to an AE

End point title	Number of participants who had study drug discontinued due to an AE ^[4]
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End point description:

An adverse event is defined as any untoward medical occurrence in a patient or clinical investigation participant administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment. Analysis population included all participants who received at least 1 dose of study drug, categorized according to the treatment actually received.

End point type	Primary
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End point timeframe:

Up to 16 weeks

Notes:

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

Justification: No statistical analyses were planned for this endpoint.

End point values	A1: GT3 NC TN Grazoprevir+Uprifosbuvir+Elbasvir (8 weeks)	A2: GT3 NC TN Grazoprevir+Uprifosbuvir+Ruzasvir (8 weeks)	A3: GT3 NC TN Grazoprevir+Uprifosbuvir+Elbasvir (8 weeks)	A4: GT3 NC TN Grazoprevir+Uprifosbuvir+Ruzasvir (8 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	21	22	22
Units: Participants	0	0	0	0

End point values	B4: GT3 NC TN MK-3682B (8 weeks)	B5: GT3 NC TN MK-3682B + RBV (8 weeks)	B6: GT3 NC TN MK-3682B (12 weeks)	B7: GT3 NC TN MK-3682B + RBV (12 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	36	37	35
Units: Participants	0	0	0	1

End point values	B8: GT3 NC TE MK-3682B (8 weeks)	B9: GT3 NC TE MK-3682B + RBV (8 weeks)	B10: GT3 NC TE MK-3682B (12 weeks)	B11: GT3 NC TE MK-3682B + RBV (12 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	14	14	15
Units: Participants	0	0	0	0

End point values	B12: GT3 NC TE MK-3682B (16 weeks)	B13: GT3 C TN MK-3682B (12 weeks)	B14: GT3 C TN MK-3682B + RBV (12 weeks)	B15: GT3 C TN MK-3682B (16 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	13	16	14
Units: Participants	0	0	1	1

End point values	B16: GT3 C TE MK-3682B (12 weeks)	B17: GT3 C TE MK-3682B + RBV (12 weeks)	B18: GT3 C TE MK-3682B (16 weeks)	B19: GT3 C TE MK-3682B + RBV (16 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	14	20	25
Units: Participants	0	0	1	0

End point values	B20: GT4 NC TN MK-3682B (8 weeks)	B22: GT6 NC TN MK-3682B (12 weeks)	A4+B4: GT3 NC TN MK-3682B (8 weeks)	Part C: GT3 NC TN: MK-3682B + RBV (16 weeks)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	7	4	38	8
Units: Participants	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of GT3-infected participants achieving SVR at follow-up Week 24 (SVR24)

End point title	Percentage of GT3-infected participants achieving SVR at follow-up Week 24 (SVR24) ^[5]
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End point description:

SVR24 is defined as HCV RNA <LLOQ of 15 IU/mL 24 weeks after the end of all study therapy. A4+B4: GT3 NC TN MK-3682B (8 weeks) arm includes both participants from Part A and Part B who received equivalent dose of MK-3682B. Analysis population included HCV GT3 participants who received treatment and did not have major protocol deviations that may substantially affect the results of the SVR endpoints. Therefore, only GT3 treatment arms are presented in the table below.

End point type	Secondary
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End point timeframe:

Up to 40 weeks

Notes:

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

Justification: Analysis population included HCV GT3 participants who received treatment and did not have major protocol deviations that may substantially affect the results of the SVR endpoints.

End point values	A1: GT3 NC TN Grazoprevir+U prifosbuvir+Elb asvir (8 weeks)	A2: GT3 NC TN Grazoprevir+U prifosbuvir+Ru zasvir (8 weeks)	A3: GT3 NC TN Grazoprevir+U prifosbuvir+Elb asvir (8 weeks)	A4: GT3 NC TN Grazoprevir+U prifosbuvir+Ru zasvir (8 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	21	22	22
Units: Percentage of participants				
number (confidence interval 95%)	90.0 (68.3 to 98.8)	95.2 (76.2 to 99.9)	86.4 (65.1 to 97.1)	90.9 (70.8 to 98.9)

End point values	B4: GT3 NC TN MK-3682B (8 weeks)	B5: GT3 NC TN MK-3682B + RBV (8 weeks)	B6: GT3 NC TN MK-3682B (12 weeks)	B7: GT3 NC TN MK-3682B + RBV (12 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	33	36	34
Units: Percentage of participants				
number (confidence interval 95%)	93.8 (69.8 to 99.8)	100.0 (89.4 to 100.0)	97.2 (85.5 to 99.9)	100.0 (89.7 to 100.0)

End point values	B8: GT3 NC TE	B9: GT3 NC TE	B10: GT3 NC	B11: GT3 NC
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	MK-3682B (8 weeks)	MK-3682B + RBV (8 weeks)	TE MK-3682B (12 weeks)	TE MK-3682B + RBV (12 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	14	14	15
Units: Percentage of participants				
number (confidence interval 95%)	100.0 (78.2 to 100.0)	92.9 (66.1 to 99.8)	100.0 (76.8 to 100.0)	93.3 (68.1 to 99.8)

End point values	B12: GT3 NC TE MK-3682B (16 weeks)	B13: GT3 C TN MK-3682B (12 weeks)	B14: GT3 C TN MK-3682B + RBV (12 weeks)	B15: GT3 C TN MK-3682B (16 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	13	16	13
Units: Percentage of participants				
number (confidence interval 95%)	93.8 (69.8 to 99.8)	92.3 (64.0 to 99.8)	100.0 (79.4 to 100.0)	100.0 (75.3 to 100.0)

End point values	B16: GT3 C TE MK-3682B (12 weeks)	B17: GT3 C TE MK-3682B + RBV (12 weeks)	B18: GT3 C TE MK-3682B (16 weeks)	B19: GT3 C TE MK-3682B + RBV (16 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	13	20	25
Units: Percentage of participants				
number (confidence interval 95%)	100.0 (78.2 to 100.0)	100.0 (75.3 to 100.0)	100.0 (83.2 to 100.0)	96.0 (79.6 to 99.9)

End point values	A4+B4: GT3 NC TN MK-3682B (8 weeks)			
Subject group type	Subject analysis set			
Number of subjects analysed	38			
Units: Percentage of participants				
number (confidence interval 95%)	92.1 (78.6 to 98.3)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 80 weeks (Parts A and B: 8 weeks or up to 16 weeks of treatment, respectively, plus 24-week follow-up; Part C: up to 16 weeks of retreatment plus 24-week follow-up)

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	20.0
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Reporting groups

Reporting group title	A1: GT3 NC TN EBR+GZR+UPR300 (8 wks)
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Reporting group description:

In Part A, participants received grazoprevir (100 mg) + uprifosbuvir (300 mg) + elbasvir (50 mg) q.d. by mouth for 8 weeks.

Reporting group title	A1+C: GT3 NC TN EBR+GZR+UPR300 (8 wks); MK-3682B+RBV (16 wks)
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Reporting group description:

In Part A, participants received grazoprevir (100 mg) + uprifosbuvir 300 mg + elbasvir (50 mg) q.d. by mouth for 8 weeks. In Part C, participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. and RBV (weight-based dosing) b.i.d. by mouth for 16 weeks.

Reporting group title	A2: GT3 NC TN GZR+RZR+UPR300 (8 wks)
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Reporting group description:

In Part A, participants received grazoprevir (100 mg) + uprifosbuvir (300 mg) + ruzasvir (60 mg) q.d. by mouth for 8 weeks.

Reporting group title	A2+C: GT3 NC TN GZR+RZR+UPR300 (8 wks); MK-3682B+RBV (16 wks)
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Reporting group description:

In Part A, participants received grazoprevir (100 mg) + uprifosbuvir (300 mg) + ruzasvir (60 mg) q.d. by mouth for 8 weeks. In Part C, participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. and RBV (weight-based dosing) b.i.d. by mouth for 16 weeks.

Reporting group title	A3: GT3 NC TN EBR+GZR+UPR450 (8 wks)
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Reporting group description:

In Part A, participants received grazoprevir (100 mg) + uprifosbuvir (450 mg) + elbasvir (50 mg) q.d. by mouth for 8 weeks.

Reporting group title	A4: GT3 NC TN GZR+RZR+UPR450 (8 wks)
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Reporting group description:

In Part A, participants received grazoprevir 100 mg + uprifosbuvir 450 mg + ruzasvir 60 mg q.d. by mouth for 8 weeks.

Reporting group title	A3+C: GT3 NC TN EBR+GZR+UPR450 (8 wks); MK-3682B+RBV (16 wks)
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Reporting group description:

In Part A, participants received grazoprevir (100 mg) + uprifosbuvir (450 mg) + elbasvir (50 mg) q.d. by mouth for 8 weeks. In Part C, participants received MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. and RBV (weight-based dosing) b.i.d. by mouth for 16 weeks.

Reporting group title	B4: GT3 NC TN MK-3682B (8 wks)
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Reporting group description:

In Part B, participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 8 weeks.

Reporting group title	A4+C: GT3 NC TN GZR+RZR+UPR450 (8 wks); MK-3682B+RBV (16 wks)
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Reporting group description:

In Part A, participants received grazoprevir 100 mg + uprifosbuvir 450 mg + ruzasvir 60 mg q.d. by

mouth for 8 weeks. In Part C, participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. and RBV (weight-based dosing) b.i.d. by mouth for 16 weeks.

Reporting group title	B5: GT3 NC TN MK-3682B + RBV (8 wks)
Reporting group description: In Part B , participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 8 weeks.	
Reporting group title	B7: GT3 NC TN MK-3682B + RBV (12 wks)
Reporting group description: In Part B, HCV GT3-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 12 weeks.	
Reporting group title	B6: GT3 NC TN MK-3682B (12 wks)
Reporting group description: In Part B, HCV GT3-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.	
Reporting group title	B8: GT3 NC TE MK-3682B (8 wks)
Reporting group description: In Part B, HCV GT3-infected NC TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 8 weeks.	
Reporting group title	B9: GT3 NC TE MK-3682B + RBV (8 wks)
Reporting group description: In Part B, HCV GT3-infected NC TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 8 weeks.	
Reporting group title	B10: GT3 NC TE MK-3682B (12 wks)
Reporting group description: In Part B, HCV GT3-infected NC TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.	
Reporting group title	B11: GT3 NC TE MK-3682B + RBV (12 wks)
Reporting group description: In Part B, HCV GT3-infected NC TE participants received 2 MK-3682 FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 12 weeks.	
Reporting group title	B12: GT3 NC TE MK-3682B (16 wks)
Reporting group description: In Part B, HCV GT3-infected NC TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 16 weeks.	
Reporting group title	B13: GT3 C TN MK-3682B (12 wks)
Reporting group description: In Part B, HCV GT3-infected C TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.	
Reporting group title	B14: GT3 C TN MK-3682B + RBV (12 wks)
Reporting group description: In Part B, HCV GT3-infected C TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 12 weeks.	
Reporting group title	B15: GT3 C TN MK-3682B (16 wks)
Reporting group description: In Part B, HCV GT3-infected C TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 16 weeks.	
Reporting group title	B16: GT3 C TE MK-3682B (12 wks)
Reporting group description: In Part B, HCV GT3-infected C TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.	
Reporting group title	B17: GT3 C TE MK-3682B + RBV (12 wks)

Reporting group description:

In Part B, HCV GT3-infected C TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 12 weeks.

Reporting group title	B18: GT3 C TE MK-3682B (16 wks)
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Reporting group description:

In Part B, HCV GT3-infected C TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 16 weeks.

Reporting group title	B19: GT3 C TE MK-3682B + RBV (16 wks)
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Reporting group description:

In Part B, HCV GT3-infected C TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 16 weeks.

Reporting group title	B20: GT4 NC TN MK-3682B (8 wks)
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Reporting group description:

In Part B, HCV GT4-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 8 weeks.

Reporting group title	B22: GT6 NC TN MK-3682B (12 wks)
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Reporting group description:

In Part B, HCV GT6-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks.

Serious adverse events	A1: GT3 NC TN EBR+GZR+UPR300 (8 wks)	A1+C: GT3 NC TN EBR+GZR+UPR300 (8 wks); MK- 3682B+RBV (16 wks)	A2: GT3 NC TN GZR+RZR+UPR300 (8 wks)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 19 (5.26%)	0 / 2 (0.00%)	0 / 20 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Blood sodium decreased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory pseudotumour			

subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip and/or oral cavity cancer stage 0			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Tendon rupture			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
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			
Coronary artery disease			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Keratitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain lower			

subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
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			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
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			
Pharyngeal abscess			
subjects affected / exposed	1 / 19 (5.26%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serious adverse events			
	A2+C: GT3 NC TN GZR+RZR+UPR300 (8 wks); MK- 3682B+RBV (16	A3: GT3 NC TN EBR+GZR+UPR450 (8 wks)	A4: GT3 NC TN GZR+RZR+UPR450 (8 wks)

	wks)		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Blood sodium decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory pseudotumour			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip and/or oral cavity cancer stage 0			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Tendon rupture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Coronary artery disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral haemorrhage			

subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Keratitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			

subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pharyngeal abscess			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	A3+C: GT3 NC TN EBR+GZR+UPR450 (8 wks); MK-3682B+RBV (16 wks)	B4: GT3 NC TN MK-3682B (8 wks)	A4+C: GT3 NC TN GZR+RZR+UPR450 (8 wks); MK-3682B+RBV (16 wks)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	1 / 2 (50.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Blood sodium decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (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
Inflammatory pseudotumour			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (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
Lip and/or oral cavity cancer stage 0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Tendon rupture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (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			
Coronary artery disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (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			
Cerebral haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (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
Migraine			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Keratitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary colic			

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (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
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (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
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (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			
Pharyngeal abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	B5: GT3 NC TN MK-3682B + RBV (8 wks)	B7: GT3 NC TN MK-3682B + RBV (12 wks)	B6: GT3 NC TN MK-3682B (12 wks)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 36 (2.78%)	1 / 35 (2.86%)	0 / 37 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Blood sodium decreased			

subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory pseudotumour			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip and/or oral cavity cancer stage 0			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Tendon rupture			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
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			
Coronary artery disease			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			

subjects affected / exposed	0 / 36 (0.00%)	1 / 35 (2.86%)	0 / 37 (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
Eye disorders			
Keratitis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
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			
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 36 (2.78%)	0 / 35 (0.00%)	0 / 37 (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
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			

subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
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			
Pharyngeal abscess			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
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			
	B8: GT3 NC TE MK-3682B (8 wks)	B9: GT3 NC TE MK-3682B + RBV (8 wks)	B10: GT3 NC TE MK-3682B (12 wks)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Blood sodium decreased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory pseudotumour			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip and/or oral cavity cancer stage 0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Tendon rupture			

subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
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			
Coronary artery disease			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Keratitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
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			
Chronic obstructive pulmonary disease			

subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
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			
Pharyngeal abscess			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
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	B11: GT3 NC TE MK-3682B + RBV (12 wks)	B12: GT3 NC TE MK-3682B (16 wks)	B13: GT3 C TN MK-3682B (12 wks)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	1 / 13 (7.69%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Blood sodium decreased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (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
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			

subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory pseudotumour			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (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
Lip and/or oral cavity cancer stage 0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (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
Injury, poisoning and procedural complications			
Tendon rupture			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	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
Cardiac disorders			
Coronary artery disease			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (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
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (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
Migraine			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (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
Eye disorders			
Keratitis			

subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (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
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (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
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (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			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (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
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (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
Anxiety			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (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
Mental status changes			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (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
Infections and infestations			
Pharyngeal abscess			

subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (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	B14: GT3 C TN MK-3682B + RBV (12 wks)	B15: GT3 C TN MK-3682B (16 wks)	B16: GT3 C TE MK-3682B (12 wks)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 16 (0.00%)	2 / 14 (14.29%)	2 / 15 (13.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Blood sodium decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory pseudotumour			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 15 (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
Lip and/or oral cavity cancer stage 0			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Tendon rupture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
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			
Coronary artery disease			

subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Keratitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
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			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Alcohol abuse			

subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 15 (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
Infections and infestations			
Pharyngeal abscess			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
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	B17: GT3 C TE MK-3682B + RBV (12 wks)	B18: GT3 C TE MK-3682B (16 wks)	B19: GT3 C TE MK-3682B + RBV (16 wks)
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 14 (14.29%)	2 / 20 (10.00%)	1 / 25 (4.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Blood sodium decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory pseudotumour			

subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip and/or oral cavity cancer stage 0			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Tendon rupture			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
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			
Coronary artery disease			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 25 (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
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 25 (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
Migraine			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Keratitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain lower			

subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
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			
Pharyngeal abscess			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
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	B20: GT4 NC TN MK-3682B (8 wks)	B22: GT6 NC TN MK-3682B (12 wks)	
Total subjects affected by serious adverse events			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Investigations			
Blood sodium decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammatory pseudotumour			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lip and/or oral cavity cancer stage 0			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Tendon rupture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Coronary artery disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (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			
Cerebral haemorrhage			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Keratitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (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			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (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			
Pharyngeal abscess			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	A1: GT3 NC TN EBR+GZR+UPR300 (8 wks)	A1+C: GT3 NC TN EBR+GZR+UPR300 (8 wks); MK- 3682B+RBV (16 wks)	A2: GT3 NC TN GZR+RZR+UPR300 (8 wks)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 19 (89.47%)	1 / 2 (50.00%)	12 / 20 (60.00%)
Vascular disorders			
Arteriosclerosis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Chest discomfort			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Energy increased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	4 / 19 (21.05%)	0 / 2 (0.00%)	5 / 20 (25.00%)
occurrences (all)	4	0	5
Feeling abnormal			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Feeling jittery			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 19 (5.26%)	0 / 2 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Local swelling			
subjects affected / exposed	1 / 19 (5.26%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0

Malaise subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Pain subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Vessel puncture site pain subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Reproductive system and breast disorders Breast tenderness subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Erectile dysfunction subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Vulval haematoma subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Chronic obstructive pulmonary disease subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Dry throat			

subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nasal discomfort			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Rhinorrhoea			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			

subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	1 / 19 (5.26%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Affect lability			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	1 / 19 (5.26%)	0 / 2 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Depression			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Emotional disorder			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	2 / 19 (10.53%)	0 / 2 (0.00%)	1 / 20 (5.00%)
occurrences (all)	3	0	2
Irritability			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Panic attack			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tearfulness			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bacterial test positive			
subjects affected / exposed	1 / 19 (5.26%)	0 / 2 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Blood bilirubin increased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 19 (5.26%)	0 / 2 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Blood creatinine increased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			
subjects affected / exposed	1 / 19 (5.26%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Blood urine present			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 19 (0.00%)	1 / 2 (50.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Heart rate increased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lipase increased			

subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Protein urine present			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
White blood cells urine positive			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Arthropod sting			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bone contusion			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Foot fracture			

subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Foreign body			
subjects affected / exposed	1 / 19 (5.26%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Ligament sprain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tendon injury			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bundle branch block right			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0

Tachycardia subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Nervous system disorders			
Disturbance in attention subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	0 / 2 (0.00%) 0	1 / 20 (5.00%) 1
Dizziness postural subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Dysgeusia subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	0 / 2 (0.00%) 0	1 / 20 (5.00%) 1
Dyskinesia subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	4 / 19 (21.05%) 5	1 / 2 (50.00%) 3	5 / 20 (25.00%) 6
Hypersomnia subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Lethargy subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Memory impairment subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Migraine subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Paraesthesia			

subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Poor quality sleep			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Haemolysis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Haemolytic anaemia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Tinnitus			

subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Eye disorders			
Dry eye subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Eye pain subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Ocular discomfort subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Pinguecula subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Vision blurred subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Visual impairment subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Gastrointestinal disorders			
Abdominal discomfort subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Abdominal distension subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	0 / 2 (0.00%) 0	1 / 20 (5.00%) 1
Abdominal pain upper			

subjects affected / exposed	1 / 19 (5.26%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Dental caries			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	2 / 19 (10.53%)	0 / 2 (0.00%)	1 / 20 (5.00%)
occurrences (all)	2	0	1
Diverticulum			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	1 / 19 (5.26%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Faeces soft			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	2 / 19 (10.53%)	0 / 2 (0.00%)	2 / 20 (10.00%)
occurrences (all)	2	0	2
Frequent bowel movements			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			

subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Hiatus hernia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Infrequent bowel movements			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	1 / 19 (5.26%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Lip dry			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 19 (10.53%)	0 / 2 (0.00%)	1 / 20 (5.00%)
occurrences (all)	3	0	1
Oral pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Actinic keratosis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Dermatitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	1 / 19 (5.26%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Erythema			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Photosensitivity reaction subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Pruritus subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	1 / 20 (5.00%) 1
Rash subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	1 / 20 (5.00%) 1
Rash erythematous subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Rash macular subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Rash maculo-papular subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Skin discolouration subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Skin lesion subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Urticaria subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Renal and urinary disorders			
Nephrolithiasis subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Nephropathy subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Renal cyst			

subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Ankylosing spondylitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	2 / 19 (10.53%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Back pain			
subjects affected / exposed	1 / 19 (5.26%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Fibromyalgia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Groin pain			
subjects affected / exposed	1 / 19 (5.26%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Intervertebral disc degeneration			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			

subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	2 / 19 (10.53%)	0 / 2 (0.00%)	1 / 20 (5.00%)
occurrences (all)	2	0	1
Neck pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 19 (5.26%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Plantar fasciitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rhabdomyolysis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Cellulitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0

Genital herpes			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Infected dermal cyst			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 19 (5.26%)	1 / 2 (50.00%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Pharyngitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	1 / 19 (5.26%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Tooth infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	1 / 19 (5.26%)	0 / 2 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Urinary tract infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 19 (5.26%)	0 / 2 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0

Wound infection staphylococcal subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Gout subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Hyperamylasaemia subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Hyperlipasaemia subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Hyperlipidaemia subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	1 / 20 (5.00%) 1
Hypokalaemia subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Increased appetite subjects affected / exposed occurrences (all)	2 / 19 (10.53%) 2	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0
Vitamin D deficiency subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 2 (0.00%) 0	0 / 20 (0.00%) 0

Non-serious adverse events	A2+C: GT3 NC TN GZR+RZR+UPR300 (8 wks); MK- 3682B+RBV (16 wks)	A3: GT3 NC TN EBR+GZR+UPR450 (8 wks)	A4: GT3 NC TN GZR+RZR+UPR450 (8 wks)
Total subjects affected by non-serious adverse events subjects affected / exposed	1 / 1 (100.00%)	13 / 19 (68.42%)	16 / 20 (80.00%)

Vascular disorders			
Arteriosclerosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Chest discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Energy increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	4 / 19 (21.05%)	4 / 20 (20.00%)
occurrences (all)	0	4	4
Feeling abnormal			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Feeling cold			

subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Feeling hot			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Feeling jittery			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Local swelling			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast tenderness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			

subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vulval haematoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 1 (100.00%)	2 / 19 (10.53%)	0 / 20 (0.00%)
occurrences (all)	1	2	0
Dry throat			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Nasal discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			

subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Affect lability			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Depressed mood			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Depression			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Emotional disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Insomnia			
subjects affected / exposed	1 / 1 (100.00%)	2 / 19 (10.53%)	1 / 20 (5.00%)
occurrences (all)	2	2	1
Irritability			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Panic attack			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Tearfulness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Amylase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bacterial test positive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			

subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood urine present			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Haemoglobin decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Protein urine present			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Transaminases increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
White blood cells urine positive			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	1 / 1 (100.00%)	3 / 19 (15.79%)	1 / 20 (5.00%)
occurrences (all)	1	3	1
Arthropod bite			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Arthropod sting			

subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bone contusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Foreign body			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tendon injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Arrhythmia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bundle branch block right			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	0 / 1 (0.00%)	2 / 19 (10.53%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Dizziness			
subjects affected / exposed	1 / 1 (100.00%)	1 / 19 (5.26%)	1 / 20 (5.00%)
occurrences (all)	1	1	1
Dizziness postural			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Dyskinesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Headache			

subjects affected / exposed	1 / 1 (100.00%)	5 / 19 (26.32%)	5 / 20 (25.00%)
occurrences (all)	2	8	6
Hypersomnia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	1 / 1 (100.00%)	1 / 19 (5.26%)	1 / 20 (5.00%)
occurrences (all)	1	1	1
Memory impairment			
subjects affected / exposed	1 / 1 (100.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Migraine			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Poor quality sleep			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Haemolysis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Haemolytic anaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Vertigo			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ocular discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pinguecula			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Visual impairment			

subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 19 (0.00%) 0	0 / 20 (0.00%) 0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Abdominal distension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	1 / 1 (100.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Aphthous ulcer			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Dental caries			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 1 (100.00%)	0 / 19 (0.00%)	3 / 20 (15.00%)
occurrences (all)	1	0	3
Diverticulum			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Dyspepsia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	1 / 20 (5.00%)
occurrences (all)	0	1	1

Faeces soft			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Frequent bowel movements			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Hiatus hernia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Infrequent bowel movements			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 1 (100.00%)	5 / 19 (26.32%)	6 / 20 (30.00%)
occurrences (all)	1	6	6
Oral pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Paraesthesia oral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Salivary hypersecretion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	3 / 20 (15.00%)
occurrences (all)	0	1	3
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Actinic keratosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Dermatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Ecchymosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Erythema			

subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Photosensitivity reaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Rash			
subjects affected / exposed	1 / 1 (100.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Rash erythematous			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin discolouration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin lesion			

subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nephropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Renal cyst			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Ankylosing spondylitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	1 / 1 (100.00%)	1 / 19 (5.26%)	2 / 20 (10.00%)
occurrences (all)	1	1	3
Back pain			
subjects affected / exposed	0 / 1 (0.00%)	2 / 19 (10.53%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Fibromyalgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc degeneration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Joint swelling			

subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Plantar fasciitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rhabdomyolysis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Cellulitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Genital herpes			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Infected dermal cyst			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Oral herpes			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Pharyngitis streptococcal			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 1 (100.00%) 1	0 / 19 (0.00%) 0	1 / 20 (5.00%) 1
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 19 (5.26%) 1	0 / 20 (0.00%) 0
Viral infection subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 19 (0.00%) 0	0 / 20 (0.00%) 0
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	2 / 19 (10.53%) 3	2 / 20 (10.00%) 3
Wound infection staphylococcal subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 19 (5.26%) 1	0 / 20 (0.00%) 0
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 19 (5.26%) 1	0 / 20 (0.00%) 0
Gout subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 19 (0.00%) 0	0 / 20 (0.00%) 0
Hyperamylasaemia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 19 (5.26%) 1	0 / 20 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 19 (0.00%) 0	0 / 20 (0.00%) 0
Hyperlipasaemia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 19 (5.26%) 1	0 / 20 (0.00%) 0
Hyperlipidaemia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 19 (0.00%) 0	0 / 20 (0.00%) 0
Hypokalaemia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Increased appetite			
subjects affected / exposed	0 / 1 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Vitamin D deficiency			
subjects affected / exposed	0 / 1 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	A3+C: GT3 NC TN EBR+GZR+UPR450 (8 wks); MK- 3682B+RBV (16 wks)	B4: GT3 NC TN MK- 3682B (8 wks)	A4+C: GT3 NC TN GZR+RZR+UPR450 (8 wks); MK- 3682B+RBV (16 wks)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	9 / 16 (56.25%)	2 / 2 (100.00%)
Vascular disorders			
Arteriosclerosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chest pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Energy increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 3 (33.33%)	2 / 16 (12.50%)	1 / 2 (50.00%)
occurrences (all)	1	2	2
Feeling abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Feeling jittery			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Local swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pyrexia			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Vessel puncture site pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Reproductive system and breast disorders Breast tenderness subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Erectile dysfunction subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Vulval haematoma subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Chronic obstructive pulmonary disease subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Dry throat subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Dysphonia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Dyspnoea subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0

Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Affect lability			

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Emotional disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	1 / 3 (33.33%)	1 / 16 (6.25%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Panic attack			
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Sleep disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tearfulness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bacterial test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood urine present			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Protein urine present			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
White blood cells urine positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Arthropod sting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bone contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Foreign body			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Rib fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tendon injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Bundle branch block right			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Disturbance in attention			

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Dizziness postural			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyskinesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 3 (0.00%)	5 / 16 (31.25%)	1 / 2 (50.00%)
occurrences (all)	0	6	1
Hypersomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Memory impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Poor quality sleep			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Sciatica subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Somnolence subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Tension headache subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Haemolysis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Haemolytic anaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Lymph node pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Ear and labyrinth disorders Tinnitus subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Eye disorders			

Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ocular discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pinguecula			
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Aphthous ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Constipation			

subjects affected / exposed	2 / 3 (66.67%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Dental caries			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	2 / 16 (12.50%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Diverticulum			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Faeces soft			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hiatus hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infrequent bowel movements			

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	2 / 16 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Oral pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 3 (33.33%)	2 / 16 (12.50%)	0 / 2 (0.00%)
occurrences (all)	1	3	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Actinic keratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	1

Dermatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Ecchymosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 2 (0.00%)
occurrences (all)	0	1	0

Rash			
subjects affected / exposed	2 / 3 (66.67%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Rash erythematous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin discolouration			
subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Skin lesion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nephropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal cyst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Ankylosing spondylitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Arthralgia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 16 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Fibromyalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc degeneration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Plantar fasciitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rhabdomyolysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 16 (6.25%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Genital herpes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Hordeolum			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infected dermal cyst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 3 (33.33%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Respiratory tract infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Rhinitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Sinusitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Tooth abscess subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Tooth infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 16 (6.25%) 1	0 / 2 (0.00%) 0
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Viral infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	1 / 2 (50.00%) 1
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 2	2 / 16 (12.50%) 2	0 / 2 (0.00%) 0
Wound infection staphylococcal subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0	0 / 2 (0.00%) 0
Gout			

subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperamylasaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperlipasaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Increased appetite			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	B5: GT3 NC TN MK-3682B + RBV (8 wks)	B7: GT3 NC TN MK-3682B + RBV (12 wks)	B6: GT3 NC TN MK-3682B (12 wks)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	30 / 36 (83.33%)	32 / 35 (91.43%)	24 / 37 (64.86%)
Vascular disorders			
Arteriosclerosis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hot flush			

subjects affected / exposed	0 / 36 (0.00%)	1 / 35 (2.86%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Hypertension			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	3 / 36 (8.33%)	3 / 35 (8.57%)	3 / 37 (8.11%)
occurrences (all)	3	3	3
Chest discomfort			
subjects affected / exposed	1 / 36 (2.78%)	1 / 35 (2.86%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
Chest pain			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	1 / 36 (2.78%)	1 / 35 (2.86%)	1 / 37 (2.70%)
occurrences (all)	1	1	1
Energy increased			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	10 / 36 (27.78%)	13 / 35 (37.14%)	5 / 37 (13.51%)
occurrences (all)	11	13	5
Feeling abnormal			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	1 / 36 (2.78%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Feeling hot			
subjects affected / exposed	1 / 36 (2.78%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Feeling jittery			

subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Local swelling			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	2 / 36 (5.56%)	1 / 35 (2.86%)	2 / 37 (5.41%)
occurrences (all)	2	1	2
Pyrexia			
subjects affected / exposed	0 / 36 (0.00%)	3 / 35 (8.57%)	3 / 37 (8.11%)
occurrences (all)	0	3	3
Vessel puncture site pain			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast tenderness			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Vulval haematoma			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	3 / 36 (8.33%)	2 / 35 (5.71%)	1 / 37 (2.70%)
occurrences (all)	3	2	1
Dry throat			
subjects affected / exposed	0 / 36 (0.00%)	1 / 35 (2.86%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Dysphonia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 36 (0.00%)	2 / 35 (5.71%)	0 / 37 (0.00%)
occurrences (all)	0	2	0
Dyspnoea exertional			
subjects affected / exposed	3 / 36 (8.33%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	3	0	0
Epistaxis			
subjects affected / exposed	0 / 36 (0.00%)	1 / 35 (2.86%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Nasal discomfort			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 36 (0.00%)	2 / 35 (5.71%)	1 / 37 (2.70%)
occurrences (all)	0	2	1
Paranasal sinus discomfort			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Productive cough			

subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Rhinitis allergic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 36 (2.78%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Sinus congestion			
subjects affected / exposed	0 / 36 (0.00%)	1 / 35 (2.86%)	1 / 37 (2.70%)
occurrences (all)	0	1	1
Throat irritation			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Psychiatric disorders			
Affect lability			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	2 / 36 (5.56%)	0 / 35 (0.00%)	2 / 37 (5.41%)
occurrences (all)	2	0	2
Depressed mood			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 36 (0.00%)	3 / 35 (8.57%)	3 / 37 (8.11%)
occurrences (all)	0	3	3
Emotional disorder			
subjects affected / exposed	1 / 36 (2.78%)	2 / 35 (5.71%)	0 / 37 (0.00%)
occurrences (all)	1	2	0
Insomnia			
subjects affected / exposed	3 / 36 (8.33%)	3 / 35 (8.57%)	2 / 37 (5.41%)
occurrences (all)	3	3	2
Irritability			
subjects affected / exposed	3 / 36 (8.33%)	3 / 35 (8.57%)	0 / 37 (0.00%)
occurrences (all)	3	3	0

Panic attack			
subjects affected / exposed	0 / 36 (0.00%)	1 / 35 (2.86%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Sleep disorder			
subjects affected / exposed	2 / 36 (5.56%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	2	0	0
Tearfulness			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Bacterial test positive			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	1 / 36 (2.78%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Blood urine present			

subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 36 (0.00%)	1 / 35 (2.86%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Heart rate increased			
subjects affected / exposed	0 / 36 (0.00%)	2 / 35 (5.71%)	0 / 37 (0.00%)
occurrences (all)	0	2	0
Lipase increased			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Protein urine present			
subjects affected / exposed	0 / 36 (0.00%)	1 / 35 (2.86%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Transaminases increased			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
White blood cells urine positive			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	8 / 36 (22.22%)	5 / 35 (14.29%)	1 / 37 (2.70%)
occurrences (all)	8	5	1
Arthropod bite			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Arthropod sting			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Bone contusion			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			

subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	1 / 36 (2.78%)	1 / 35 (2.86%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
Foot fracture			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Foreign body			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Tendon injury			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0

Bundle branch block right subjects affected / exposed occurrences (all)	0 / 36 (0.00%) 0	0 / 35 (0.00%) 0	0 / 37 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	2 / 36 (5.56%) 2	0 / 35 (0.00%) 0	1 / 37 (2.70%) 2
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 36 (0.00%) 0	0 / 35 (0.00%) 0	0 / 37 (0.00%) 0
Tachycardia subjects affected / exposed occurrences (all)	1 / 36 (2.78%) 1	1 / 35 (2.86%) 1	0 / 37 (0.00%) 0
Nervous system disorders			
Disturbance in attention subjects affected / exposed occurrences (all)	1 / 36 (2.78%) 1	3 / 35 (8.57%) 3	0 / 37 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	2 / 36 (5.56%) 2	3 / 35 (8.57%) 3	1 / 37 (2.70%) 1
Dizziness postural subjects affected / exposed occurrences (all)	0 / 36 (0.00%) 0	0 / 35 (0.00%) 0	0 / 37 (0.00%) 0
Dysgeusia subjects affected / exposed occurrences (all)	2 / 36 (5.56%) 2	1 / 35 (2.86%) 1	2 / 37 (5.41%) 2
Dyskinesia subjects affected / exposed occurrences (all)	0 / 36 (0.00%) 0	0 / 35 (0.00%) 0	0 / 37 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	12 / 36 (33.33%) 13	8 / 35 (22.86%) 8	7 / 37 (18.92%) 7
Hypersomnia subjects affected / exposed occurrences (all)	1 / 36 (2.78%) 1	0 / 35 (0.00%) 0	0 / 37 (0.00%) 0
Lethargy			

subjects affected / exposed	0 / 36 (0.00%)	2 / 35 (5.71%)	0 / 37 (0.00%)
occurrences (all)	0	2	0
Memory impairment			
subjects affected / exposed	1 / 36 (2.78%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Migraine			
subjects affected / exposed	1 / 36 (2.78%)	2 / 35 (5.71%)	1 / 37 (2.70%)
occurrences (all)	1	2	1
Paraesthesia			
subjects affected / exposed	0 / 36 (0.00%)	1 / 35 (2.86%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Parosmia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Poor quality sleep			
subjects affected / exposed	1 / 36 (2.78%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Sciatica			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 36 (0.00%)	2 / 35 (5.71%)	1 / 37 (2.70%)
occurrences (all)	0	2	1
Haemolysis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Haemolytic anaemia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0

Lymph node pain subjects affected / exposed occurrences (all)	0 / 36 (0.00%) 0	0 / 35 (0.00%) 0	0 / 37 (0.00%) 0
Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 36 (0.00%) 0	0 / 35 (0.00%) 0	0 / 37 (0.00%) 0
Ear and labyrinth disorders			
Tinnitus subjects affected / exposed occurrences (all)	0 / 36 (0.00%) 0	1 / 35 (2.86%) 1	1 / 37 (2.70%) 1
Vertigo subjects affected / exposed occurrences (all)	1 / 36 (2.78%) 1	0 / 35 (0.00%) 0	1 / 37 (2.70%) 1
Eye disorders			
Dry eye subjects affected / exposed occurrences (all)	0 / 36 (0.00%) 0	0 / 35 (0.00%) 0	0 / 37 (0.00%) 0
Eye pain subjects affected / exposed occurrences (all)	0 / 36 (0.00%) 0	0 / 35 (0.00%) 0	0 / 37 (0.00%) 0
Ocular discomfort subjects affected / exposed occurrences (all)	0 / 36 (0.00%) 0	0 / 35 (0.00%) 0	0 / 37 (0.00%) 0
Pinguecula subjects affected / exposed occurrences (all)	0 / 36 (0.00%) 0	0 / 35 (0.00%) 0	0 / 37 (0.00%) 0
Vision blurred subjects affected / exposed occurrences (all)	1 / 36 (2.78%) 1	0 / 35 (0.00%) 0	0 / 37 (0.00%) 0
Visual impairment subjects affected / exposed occurrences (all)	0 / 36 (0.00%) 0	0 / 35 (0.00%) 0	0 / 37 (0.00%) 0
Gastrointestinal disorders			
Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 36 (0.00%) 0	1 / 35 (2.86%) 1	0 / 37 (0.00%) 0
Abdominal distension			

subjects affected / exposed	1 / 36 (2.78%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	0 / 36 (0.00%)	3 / 35 (8.57%)	1 / 37 (2.70%)
occurrences (all)	0	3	1
Abdominal pain upper			
subjects affected / exposed	2 / 36 (5.56%)	1 / 35 (2.86%)	0 / 37 (0.00%)
occurrences (all)	2	1	0
Aphthous ulcer			
subjects affected / exposed	1 / 36 (2.78%)	1 / 35 (2.86%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
Constipation			
subjects affected / exposed	0 / 36 (0.00%)	2 / 35 (5.71%)	1 / 37 (2.70%)
occurrences (all)	0	2	1
Dental caries			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	3 / 36 (8.33%)	3 / 35 (8.57%)	5 / 37 (13.51%)
occurrences (all)	3	4	6
Diverticulum			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	1 / 36 (2.78%)	2 / 35 (5.71%)	0 / 37 (0.00%)
occurrences (all)	1	2	0
Dyspepsia			
subjects affected / exposed	1 / 36 (2.78%)	3 / 35 (8.57%)	2 / 37 (5.41%)
occurrences (all)	1	3	2
Faeces soft			
subjects affected / exposed	0 / 36 (0.00%)	2 / 35 (5.71%)	0 / 37 (0.00%)
occurrences (all)	0	2	0
Flatulence			
subjects affected / exposed	2 / 36 (5.56%)	1 / 35 (2.86%)	0 / 37 (0.00%)
occurrences (all)	2	1	0
Frequent bowel movements			

subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 36 (2.78%)	0 / 35 (0.00%)	1 / 37 (2.70%)
occurrences (all)	1	0	1
Hiatus hernia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Infrequent bowel movements			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	6 / 36 (16.67%)	5 / 35 (14.29%)	4 / 37 (10.81%)
occurrences (all)	8	6	5
Oral pain			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 36 (0.00%)	1 / 35 (2.86%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Salivary hypersecretion			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	1 / 36 (2.78%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Vomiting			

subjects affected / exposed occurrences (all)	1 / 36 (2.78%) 1	3 / 35 (8.57%) 3	3 / 37 (8.11%) 3
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Actinic keratosis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	1 / 36 (2.78%)	1 / 35 (2.86%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
Dermatitis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	3 / 36 (8.33%)	2 / 35 (5.71%)	0 / 37 (0.00%)
occurrences (all)	3	2	0
Ecchymosis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	1 / 36 (2.78%)	1 / 35 (2.86%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
Erythema			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 36 (2.78%)	2 / 35 (5.71%)	0 / 37 (0.00%)
occurrences (all)	1	2	0
Hyperkeratosis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0

Macule			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 36 (0.00%)	1 / 35 (2.86%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Photosensitivity reaction			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	2 / 36 (5.56%)	2 / 35 (5.71%)	0 / 37 (0.00%)
occurrences (all)	2	2	0
Rash			
subjects affected / exposed	4 / 36 (11.11%)	2 / 35 (5.71%)	0 / 37 (0.00%)
occurrences (all)	5	2	0
Rash erythematous			
subjects affected / exposed	0 / 36 (0.00%)	1 / 35 (2.86%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Rash macular			
subjects affected / exposed	0 / 36 (0.00%)	1 / 35 (2.86%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Rash maculo-papular			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Skin discolouration			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	1 / 36 (2.78%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Urticaria			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Nephrolithiasis			

subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Nephropathy			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Renal cyst			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Ankylosing spondylitis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	2 / 36 (5.56%)	0 / 35 (0.00%)	1 / 37 (2.70%)
occurrences (all)	2	0	1
Back pain			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Fibromyalgia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc degeneration			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 36 (0.00%)	1 / 35 (2.86%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal chest pain			

subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 36 (0.00%)	3 / 35 (8.57%)	0 / 37 (0.00%)
occurrences (all)	0	4	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	2 / 36 (5.56%)	0 / 35 (0.00%)	2 / 37 (5.41%)
occurrences (all)	3	0	3
Neck pain			
subjects affected / exposed	0 / 36 (0.00%)	1 / 35 (2.86%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Plantar fasciitis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Rhabdomyolysis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Cellulitis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Cystitis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0

Ear infection			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	1 / 36 (2.78%)	2 / 35 (5.71%)	0 / 37 (0.00%)
occurrences (all)	1	2	0
Genital herpes			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Infected dermal cyst			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 36 (2.78%)	0 / 35 (0.00%)	1 / 37 (2.70%)
occurrences (all)	1	0	2
Lower respiratory tract infection			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0

Paronychia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 36 (0.00%)	1 / 35 (2.86%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 36 (0.00%)	1 / 35 (2.86%)	1 / 37 (2.70%)
occurrences (all)	0	1	1
Tooth abscess			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 36 (2.78%)	2 / 35 (5.71%)	0 / 37 (0.00%)
occurrences (all)	1	2	0
Urinary tract infection			
subjects affected / exposed	3 / 36 (8.33%)	2 / 35 (5.71%)	1 / 37 (2.70%)
occurrences (all)	3	2	1

Viral infection			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Viral upper respiratory tract infection			
subjects affected / exposed	6 / 36 (16.67%)	1 / 35 (2.86%)	4 / 37 (10.81%)
occurrences (all)	7	1	4
Wound infection staphylococcal			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 36 (2.78%)	3 / 35 (8.57%)	1 / 37 (2.70%)
occurrences (all)	1	3	1
Gout			
subjects affected / exposed	1 / 36 (2.78%)	0 / 35 (0.00%)	1 / 37 (2.70%)
occurrences (all)	1	0	1
Hyperamylasaemia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hyperlipasaemia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Increased appetite			
subjects affected / exposed	0 / 36 (0.00%)	1 / 35 (2.86%)	1 / 37 (2.70%)
occurrences (all)	0	1	1
Vitamin D deficiency			

subjects affected / exposed	0 / 36 (0.00%)	0 / 35 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	B8: GT3 NC TE MK-3682B (8 wks)	B9: GT3 NC TE MK-3682B + RBV (8 wks)	B10: GT3 NC TE MK-3682B (12 wks)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 15 (80.00%)	12 / 14 (85.71%)	9 / 14 (64.29%)
Vascular disorders			
Arteriosclerosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 14 (7.14%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Chest discomfort			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	1 / 15 (6.67%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Chills			
subjects affected / exposed	1 / 15 (6.67%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Energy increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Fatigue			

subjects affected / exposed	3 / 15 (20.00%)	5 / 14 (35.71%)	4 / 14 (28.57%)
occurrences (all)	3	6	4
Feeling abnormal			
subjects affected / exposed	0 / 15 (0.00%)	1 / 14 (7.14%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Feeling cold			
subjects affected / exposed	1 / 15 (6.67%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Feeling hot			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Feeling jittery			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 15 (6.67%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Local swelling			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	1 / 15 (6.67%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 14 (7.14%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Vessel puncture site pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1

Reproductive system and breast disorders			
Breast tenderness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Erectile dysfunction			
subjects affected / exposed	1 / 15 (6.67%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Vulval haematoma			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	3 / 15 (20.00%)	2 / 14 (14.29%)	1 / 14 (7.14%)
occurrences (all)	3	2	1
Dry throat			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 15 (0.00%)	2 / 14 (14.29%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Dyspnoea exertional			
subjects affected / exposed	0 / 15 (0.00%)	1 / 14 (7.14%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Nasal discomfort			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	2 / 15 (13.33%)	1 / 14 (7.14%)	0 / 14 (0.00%)
occurrences (all)	2	1	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 15 (0.00%)	1 / 14 (7.14%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Throat irritation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Affect lability			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 15 (0.00%)	1 / 14 (7.14%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Depressed mood			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Depression			

subjects affected / exposed	1 / 15 (6.67%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Emotional disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 14 (7.14%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Irritability			
subjects affected / exposed	1 / 15 (6.67%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Panic attack			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 15 (0.00%)	2 / 14 (14.29%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Tearfulness			
subjects affected / exposed	0 / 15 (0.00%)	1 / 14 (7.14%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Bacterial test positive			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			

subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood urine present			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 14 (7.14%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Heart rate increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Protein urine present			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
White blood cells urine positive			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Accidental overdose			
subjects affected / exposed	1 / 15 (6.67%)	6 / 14 (42.86%)	1 / 14 (7.14%)
occurrences (all)	1	6	1
Arthropod bite			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Arthropod sting			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Bone contusion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Foreign body			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 15 (0.00%)	1 / 14 (7.14%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Rib fracture			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Tendon injury subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Thermal burn subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Cardiac disorders			
Arrhythmia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 14 (7.14%) 1	0 / 14 (0.00%) 0
Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Bundle branch block right subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Tachycardia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Nervous system disorders			
Disturbance in attention subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 14 (7.14%) 1	0 / 14 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Dizziness postural subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Dysgeusia			

subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dyskinesia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 15 (13.33%)	5 / 14 (35.71%)	2 / 14 (14.29%)
occurrences (all)	2	5	2
Hypersomnia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Poor quality sleep			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Tension headache			

subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Haemolysis			
subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Haemolytic anaemia			
subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Lymph node pain			
subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Lymphadenopathy			
subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Vertigo			
subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 14 (7.14%) 1	0 / 14 (0.00%) 0
Eye disorders			
Dry eye			
subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Eye pain			
subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Ocular discomfort			
subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Pinguecula			

subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Vision blurred subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Visual impairment subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Gastrointestinal disorders			
Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Abdominal distension subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 14 (7.14%) 1	1 / 14 (7.14%) 1
Abdominal pain subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	1 / 14 (7.14%) 1
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Aphthous ulcer subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Constipation subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Dental caries subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	2 / 15 (13.33%) 2	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Diverticulum subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0

Dry mouth			
subjects affected / exposed	2 / 15 (13.33%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	3	0	0
Dyspepsia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 14 (7.14%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Faeces soft			
subjects affected / exposed	1 / 15 (6.67%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Flatulence			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 15 (0.00%)	1 / 14 (7.14%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Hiatus hernia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Infrequent bowel movements			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 15 (6.67%)	3 / 14 (21.43%)	1 / 14 (7.14%)
occurrences (all)	1	3	1

Oral pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Actinic keratosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	1 / 15 (6.67%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Ecchymosis			

subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	2 / 15 (13.33%)	2 / 14 (14.29%)	0 / 14 (0.00%)
occurrences (all)	2	2	0
Rash			
subjects affected / exposed	1 / 15 (6.67%)	2 / 14 (14.29%)	0 / 14 (0.00%)
occurrences (all)	1	2	0
Rash erythematous			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			

subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 14 (7.14%) 1	0 / 14 (0.00%) 0
Skin discolouration subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Skin lesion subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Urticaria subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Renal and urinary disorders			
Nephrolithiasis subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Nephropathy subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	1 / 14 (7.14%) 1
Renal cyst subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Ankylosing spondylitis subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	1 / 14 (7.14%) 1
Arthralgia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Back pain subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Fibromyalgia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Groin pain			

subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc degeneration			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Musculoskeletal pain			
subjects affected / exposed	1 / 15 (6.67%)	0 / 14 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Musculoskeletal stiffness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	0 / 15 (0.00%)	1 / 14 (7.14%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Plantar fasciitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rhabdomyolysis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Acute sinusitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Ear infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Genital herpes			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Infected dermal cyst			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 15 (6.67%)	1 / 14 (7.14%)	0 / 14 (0.00%)
occurrences (all)	1	1	0

Lower respiratory tract infection subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Nasopharyngitis subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Oral herpes subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	1 / 14 (7.14%) 1
Otitis media subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Paronychia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Periodontitis subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Pharyngitis subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Pharyngitis streptococcal subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Pneumonia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	1 / 14 (7.14%) 1
Respiratory tract infection subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	1 / 14 (7.14%) 2
Rhinitis subjects affected / exposed occurrences (all)	2 / 15 (13.33%) 5	0 / 14 (0.00%) 0	1 / 14 (7.14%) 2
Sinusitis subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0

Tooth abscess subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Tooth infection subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	1 / 14 (7.14%) 2	1 / 14 (7.14%) 1
Urinary tract infection subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Viral infection subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Wound infection staphylococcal subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Gout subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	1 / 14 (7.14%) 1
Hyperamylasaemia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0
Hyperlipasaemia			

subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Increased appetite			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 15 (0.00%)	0 / 14 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	B11: GT3 NC TE MK-3682B + RBV (12 wks)	B12: GT3 NC TE MK-3682B (16 wks)	B13: GT3 C TN MK-3682B (12 wks)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 15 (86.67%)	13 / 16 (81.25%)	9 / 13 (69.23%)
Vascular disorders			
Arteriosclerosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 15 (13.33%)	1 / 16 (6.25%)	1 / 13 (7.69%)
occurrences (all)	2	1	2
Chest discomfort			

subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	1 / 15 (6.67%)	1 / 16 (6.25%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Energy increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	5 / 15 (33.33%)	4 / 16 (25.00%)	3 / 13 (23.08%)
occurrences (all)	5	4	3
Feeling abnormal			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Feeling jittery			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Local swelling			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pain			

subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 16 (6.25%) 1	0 / 13 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0
Vessel puncture site pain subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0
Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0
Reproductive system and breast disorders Breast tenderness subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0
Erectile dysfunction subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0
Vulval haematoma subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Chronic obstructive pulmonary disease subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 16 (6.25%) 1	1 / 13 (7.69%) 1
Dry throat subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0
Dysphonia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0

Dyspnoea			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Dyspnoea exertional			
subjects affected / exposed	4 / 15 (26.67%)	0 / 16 (0.00%)	1 / 13 (7.69%)
occurrences (all)	4	0	1
Epistaxis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nasal discomfort			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	1 / 13 (7.69%)
occurrences (all)	0	2	1
Paranasal sinus discomfort			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Productive cough			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Rhinitis allergic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Psychiatric disorders			
Affect lability			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Emotional disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	2 / 15 (13.33%)	1 / 16 (6.25%)	0 / 13 (0.00%)
occurrences (all)	2	1	0
Irritability			
subjects affected / exposed	2 / 15 (13.33%)	0 / 16 (0.00%)	1 / 13 (7.69%)
occurrences (all)	2	0	1
Panic attack			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Tearfulness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Amylase increased			

subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Bacterial test positive			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood urine present			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Protein urine present			

subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0
Transaminases increased subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0
White blood cells urine positive subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0
Injury, poisoning and procedural complications			
Accidental overdose subjects affected / exposed occurrences (all)	2 / 15 (13.33%) 2	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0
Arthropod bite subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0
Arthropod sting subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0
Bone contusion subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0
Clavicle fracture subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0
Contusion subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0
Foot fracture subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0
Foreign body			

subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Tendon injury			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Bundle branch block right			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Palpitations			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Sinus tachycardia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 15 (6.67%)	3 / 16 (18.75%)	2 / 13 (15.38%)
occurrences (all)	1	3	2
Dizziness postural			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Dysgeusia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dyskinesia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	5 / 15 (33.33%)	6 / 16 (37.50%)	1 / 13 (7.69%)
occurrences (all)	6	6	1
Hypersomnia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Lethargy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Parosmia			

subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Poor quality sleep			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Haemolysis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Haemolytic anaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vertigo			

subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Ocular discomfort			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pinguecula			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Visual impairment			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Abdominal distension			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Abdominal pain			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Abdominal pain upper			
subjects affected / exposed	1 / 15 (6.67%)	1 / 16 (6.25%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Aphthous ulcer			

subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Dental caries			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 15 (6.67%)	4 / 16 (25.00%)	0 / 13 (0.00%)
occurrences (all)	1	4	0
Diverticulum			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Faeces soft			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 15 (0.00%)	2 / 16 (12.50%)	1 / 13 (7.69%)
occurrences (all)	0	2	1
Frequent bowel movements			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 15 (0.00%)	2 / 16 (12.50%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Hiatus hernia			

subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Infrequent bowel movements			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 15 (13.33%)	3 / 16 (18.75%)	2 / 13 (15.38%)
occurrences (all)	2	3	2
Oral pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Actinic keratosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Alopecia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Dermatitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Dermatitis contact			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Ecchymosis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Eczema			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Erythema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Photosensitivity reaction			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 13 (0.00%)
occurrences (all)	0	1	0

Pruritus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Rash erythematous			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Skin discolouration			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Nephropathy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Renal cyst			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			

Ankylosing spondylitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	0 / 15 (0.00%)	2 / 16 (12.50%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Back pain			
subjects affected / exposed	1 / 15 (6.67%)	2 / 16 (12.50%)	0 / 13 (0.00%)
occurrences (all)	1	2	0
Fibromyalgia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc degeneration			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 13 (0.00%)
occurrences (all)	0	4	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0

Neck pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Plantar fasciitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rhabdomyolysis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Cellulitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Genital herpes			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Gingivitis			

subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Herpes simplex			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Infected dermal cyst			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	1 / 15 (6.67%)	1 / 16 (6.25%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Oral herpes			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Paronychia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Periodontitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			

subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	0 / 15 (0.00%)	2 / 16 (12.50%)	0 / 13 (0.00%)
occurrences (all)	0	3	0
Tooth abscess			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Urinary tract infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 15 (0.00%)	3 / 16 (18.75%)	1 / 13 (7.69%)
occurrences (all)	0	3	1
Wound infection staphylococcal			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			

Decreased appetite subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 16 (0.00%) 0	1 / 13 (7.69%) 1
Gout subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0
Hyperamylasaemia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0
Hyperlipasaemia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0
Hyperlipidaemia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 16 (6.25%) 1	0 / 13 (0.00%) 0
Hypokalaemia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0
Increased appetite subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0
Vitamin D deficiency subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0

Non-serious adverse events	B14: GT3 C TN MK-3682B + RBV (12 wks)	B15: GT3 C TN MK-3682B (16 wks)	B16: GT3 C TE MK-3682B (12 wks)
Total subjects affected by non-serious adverse events subjects affected / exposed	14 / 16 (87.50%)	12 / 14 (85.71%)	12 / 15 (80.00%)
Vascular disorders Arteriosclerosis subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Flushing			

subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Hot flush			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Hypertension			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Chest discomfort			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Chest pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Energy increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	4 / 16 (25.00%)	3 / 14 (21.43%)	3 / 15 (20.00%)
occurrences (all)	5	3	3
Feeling abnormal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Feeling hot			

subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Feeling jittery			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
Local swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Breast tenderness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Vulval haematoma			

subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	4 / 16 (25.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	5	0	0
Dry throat			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Haemoptysis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Nasal discomfort			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			

subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Sinus congestion			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Throat irritation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Affect lability			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Anxiety			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Emotional disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0

Irritability			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Panic attack			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	1 / 16 (6.25%)	1 / 14 (7.14%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Tearfulness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Bacterial test positive			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Blood potassium increased			

subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood urine present			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Protein urine present			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
White blood cells urine positive			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	4 / 16 (25.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	4	0	0
Arthropod bite			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Arthropod sting			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Bone contusion			

subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
Fall			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Foreign body			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Muscle strain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Rib fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tendon injury			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Thermal burn			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Atrial fibrillation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Bundle branch block right			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Dizziness postural			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Dyskinesia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	4 / 16 (25.00%)	4 / 14 (28.57%)	1 / 15 (6.67%)
occurrences (all)	4	5	1
Hypersomnia			

subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
Lethargy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Poor quality sleep			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Sciatica			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Somnolence			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Haemolysis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Haemolytic anaemia subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Lymph node pain subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 14 (7.14%) 1	0 / 15 (0.00%) 0
Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Ear and labyrinth disorders Tinnitus subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 2	0 / 14 (0.00%) 0	1 / 15 (6.67%) 1
Eye disorders Dry eye subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 14 (7.14%) 1	0 / 15 (0.00%) 0
Eye pain subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Ocular discomfort subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Pinguecula subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Vision blurred subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Visual impairment subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Gastrointestinal disorders			

Abdominal discomfort			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Abdominal distension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Dental caries			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	1 / 16 (6.25%)	1 / 14 (7.14%)	3 / 15 (20.00%)
occurrences (all)	2	2	3
Diverticulum			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Dry mouth			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Faeces soft			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Flatulence			
subjects affected / exposed	0 / 16 (0.00%)	2 / 14 (14.29%)	1 / 15 (6.67%)
occurrences (all)	0	2	1
Frequent bowel movements			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Hiatus hernia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Infrequent bowel movements			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	2 / 16 (12.50%)	3 / 14 (21.43%)	1 / 15 (6.67%)
occurrences (all)	3	3	1
Oral pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Salivary hypersecretion			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0

Tongue ulceration subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	3 / 14 (21.43%) 3	0 / 15 (0.00%) 0
Skin and subcutaneous tissue disorders			
Acne subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 14 (7.14%) 1	0 / 15 (0.00%) 0
Actinic keratosis subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 14 (7.14%) 1	0 / 15 (0.00%) 0
Alopecia subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 14 (0.00%) 0	1 / 15 (6.67%) 1
Dermatitis subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Dermatitis contact subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 14 (7.14%) 1	0 / 15 (0.00%) 0
Dry skin subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Ecchymosis subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Eczema subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Erythema subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Hyperhidrosis			

subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Rash			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Rash erythematous			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Rash macular			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Skin discolouration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Urticaria			

subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Nephropathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Renal cyst			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Ankylosing spondylitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	0 / 16 (0.00%)	2 / 14 (14.29%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
Back pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Fibromyalgia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc degeneration			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Joint swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			

subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Plantar fasciitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Rhabdomyolysis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Cellulitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0

Cystitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Genital herpes			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Infected dermal cyst			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 16 (0.00%)	2 / 14 (14.29%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Oral herpes			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 15 (0.00%)
occurrences (all)	0	1	0

Otitis media			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Pharyngitis streptococcal			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Tooth abscess			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Tooth infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 16 (0.00%)	2 / 14 (14.29%)	0 / 15 (0.00%)
occurrences (all)	0	2	0

Urinary tract infection subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Viral infection subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	3 / 14 (21.43%) 3	4 / 15 (26.67%) 4
Wound infection staphylococcal subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Gout subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Hyperamylasaemia subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Hyperlipasaemia subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Hyperlipidaemia subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Hypokalaemia subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Increased appetite			

subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Vitamin D deficiency			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	B17: GT3 C TE MK-3682B + RBV (12 wks)	B18: GT3 C TE MK-3682B (16 wks)	B19: GT3 C TE MK-3682B + RBV (16 wks)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 14 (78.57%)	15 / 20 (75.00%)	21 / 25 (84.00%)
Vascular disorders			
Arteriosclerosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	2
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	3 / 14 (21.43%)	1 / 20 (5.00%)	2 / 25 (8.00%)
occurrences (all)	3	2	2
Chest discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	1 / 14 (7.14%)	1 / 20 (5.00%)	0 / 25 (0.00%)
occurrences (all)	1	1	0
Chills			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	2
Energy increased			

subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	5 / 14 (35.71%)	4 / 20 (20.00%)	9 / 25 (36.00%)
occurrences (all)	7	4	10
Feeling abnormal			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Feeling jittery			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Local swelling			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Pyrexia			
subjects affected / exposed	0 / 14 (0.00%)	3 / 20 (15.00%)	2 / 25 (8.00%)
occurrences (all)	0	3	2
Vessel puncture site pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			

Seasonal allergy subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 20 (0.00%) 0	0 / 25 (0.00%) 0
Reproductive system and breast disorders			
Breast tenderness subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 20 (0.00%) 0	0 / 25 (0.00%) 0
Erectile dysfunction subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 20 (0.00%) 0	0 / 25 (0.00%) 0
Vulval haematoma subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 20 (0.00%) 0	0 / 25 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 20 (0.00%) 0	0 / 25 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	3 / 20 (15.00%) 3	3 / 25 (12.00%) 3
Dry throat subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	0 / 20 (0.00%) 0	0 / 25 (0.00%) 0
Dysphonia subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 20 (0.00%) 0	0 / 25 (0.00%) 0
Dyspnoea subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	0 / 20 (0.00%) 0	2 / 25 (8.00%) 2
Dyspnoea exertional subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 20 (0.00%) 0	0 / 25 (0.00%) 0
Epistaxis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 20 (0.00%) 0	0 / 25 (0.00%) 0

Haemoptysis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Nasal discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Throat irritation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Affect lability			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	2
Anxiety			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Depressed mood			

subjects affected / exposed	1 / 14 (7.14%)	2 / 20 (10.00%)	0 / 25 (0.00%)
occurrences (all)	1	2	0
Depression			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Emotional disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	2 / 14 (14.29%)	1 / 20 (5.00%)	1 / 25 (4.00%)
occurrences (all)	2	1	1
Irritability			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	2 / 25 (8.00%)
occurrences (all)	0	1	2
Panic attack			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Tearfulness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Bacterial test positive			

subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Blood urine present			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Protein urine present			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
White blood cells urine positive			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0

Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	3 / 25 (12.00%)
occurrences (all)	1	0	4
Arthropod bite			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Arthropod sting			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Bone contusion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Foot fracture			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Foreign body			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Rib fracture			

subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Tendon injury			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Bundle branch block right			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Sinus tachycardia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	0 / 14 (0.00%)	2 / 20 (10.00%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Dizziness			
subjects affected / exposed	2 / 14 (14.29%)	1 / 20 (5.00%)	1 / 25 (4.00%)
occurrences (all)	2	1	1
Dizziness postural			

subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Dyskinesia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 14 (14.29%)	3 / 20 (15.00%)	9 / 25 (36.00%)
occurrences (all)	3	3	11
Hypersomnia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1
Parosmia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Poor quality sleep			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Somnolence			

subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 20 (0.00%) 0	0 / 25 (0.00%) 0
Tension headache subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 20 (0.00%) 0	0 / 25 (0.00%) 0
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 20 (0.00%) 0	0 / 25 (0.00%) 0
Haemolysis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 20 (0.00%) 0	0 / 25 (0.00%) 0
Haemolytic anaemia subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 20 (0.00%) 0	0 / 25 (0.00%) 0
Lymph node pain subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 20 (0.00%) 0	0 / 25 (0.00%) 0
Lymphadenopathy subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	0 / 20 (0.00%) 0	0 / 25 (0.00%) 0
Ear and labyrinth disorders			
Tinnitus subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 20 (0.00%) 0	0 / 25 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 20 (0.00%) 0	0 / 25 (0.00%) 0
Eye disorders			
Dry eye subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 20 (0.00%) 0	0 / 25 (0.00%) 0
Eye pain subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 20 (0.00%) 0	0 / 25 (0.00%) 0
Ocular discomfort			

subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Pinguecula			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Visual impairment			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Abdominal distension			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	3 / 25 (12.00%)
occurrences (all)	0	1	3
Abdominal pain			
subjects affected / exposed	0 / 14 (0.00%)	3 / 20 (15.00%)	1 / 25 (4.00%)
occurrences (all)	0	4	1
Abdominal pain upper			
subjects affected / exposed	2 / 14 (14.29%)	0 / 20 (0.00%)	1 / 25 (4.00%)
occurrences (all)	2	0	1
Aphthous ulcer			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	2 / 25 (8.00%)
occurrences (all)	1	0	2
Dental caries			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 14 (7.14%)	1 / 20 (5.00%)	1 / 25 (4.00%)
occurrences (all)	1	1	2

Diverticulum			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1
Faeces soft			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	2 / 14 (14.29%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Frequent bowel movements			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Hiatus hernia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Infrequent bowel movements			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0

Nausea			
subjects affected / exposed	2 / 14 (14.29%)	2 / 20 (10.00%)	4 / 25 (16.00%)
occurrences (all)	3	2	5
Oral pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Actinic keratosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Dermatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Dry skin			

subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	2 / 25 (8.00%)
occurrences (all)	0	1	2
Ecchymosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Night sweats			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	1 / 14 (7.14%)	1 / 20 (5.00%)	5 / 25 (20.00%)
occurrences (all)	1	1	5
Rash			
subjects affected / exposed	2 / 14 (14.29%)	1 / 20 (5.00%)	1 / 25 (4.00%)
occurrences (all)	3	3	1
Rash erythematous			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Rash macular			

subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Skin discolouration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Nephropathy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Renal cyst			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Ankylosing spondylitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	2 / 25 (8.00%)
occurrences (all)	0	1	2
Back pain			
subjects affected / exposed	1 / 14 (7.14%)	3 / 20 (15.00%)	0 / 25 (0.00%)
occurrences (all)	1	3	0
Fibromyalgia			

subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc degeneration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal stiffness			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Plantar fasciitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Rhabdomyolysis			

subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 20 (0.00%) 0	0 / 25 (0.00%) 0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Cystitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Genital herpes			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Hordeolum			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Infected dermal cyst			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0

Influenza			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1
Lower respiratory tract infection			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	3

Sinusitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Tooth abscess			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Viral infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	2 / 14 (14.29%)	1 / 20 (5.00%)	2 / 25 (8.00%)
occurrences (all)	2	1	2
Wound infection staphylococcal			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 14 (14.29%)	1 / 20 (5.00%)	3 / 25 (12.00%)
occurrences (all)	2	1	3
Gout			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hyperamylasaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			

subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hyperlipasaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Increased appetite			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 14 (0.00%)	2 / 20 (10.00%)	0 / 25 (0.00%)
occurrences (all)	0	2	0

Non-serious adverse events	B20: GT4 NC TN MK-3682B (8 wks)	B22: GT6 NC TN MK-3682B (12 wks)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 7 (42.86%)	3 / 4 (75.00%)	
Vascular disorders			
Arteriosclerosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Flushing			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Hot flush			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Hypertension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			

Asthenia		
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	1	0
Chest discomfort		
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0
Chest pain		
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0
Chills		
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0
Energy increased		
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0
Fatigue		
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0
Feeling abnormal		
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0
Feeling cold		
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0
Feeling hot		
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0
Feeling jittery		
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0
Influenza like illness		
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0
Local swelling		
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0

Malaise subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Pyrexia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Vessel puncture site pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Reproductive system and breast disorders Breast tenderness subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Erectile dysfunction subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Vulval haematoma subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders Chronic obstructive pulmonary disease subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Cough subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Dry throat			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Dysphonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Dyspnoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Dyspnoea exertional			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Epistaxis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Haemoptysis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Nasal discomfort			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Paranasal sinus discomfort			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Productive cough			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Rhinitis allergic			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Rhinorrhoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Sinus congestion			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Throat irritation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Affect lability			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Anxiety			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Depressed mood			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Depression			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Emotional disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Insomnia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Irritability			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Panic attack			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Sleep disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Tearfulness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	

Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Amylase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Bacterial test positive			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Blood bilirubin increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Blood creatinine increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Blood potassium increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Blood urine present			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Haemoglobin decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Heart rate increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Lipase increased			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Protein urine present			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Transaminases increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
White blood cells urine positive			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Arthropod bite			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Arthropod sting			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Bone contusion			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Clavicle fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Contusion			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Fall			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Foot fracture			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Foreign body			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Ligament sprain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Muscle strain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Rib fracture			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Tendon injury			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Thermal burn			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Atrial fibrillation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Bundle branch block right			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Palpitations			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Sinus tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	

Tachycardia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Nervous system disorders			
Disturbance in attention subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Dizziness subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Dizziness postural subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Dysgeusia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Dyskinesia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Headache subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	2 / 4 (50.00%) 2	
Hypersomnia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Lethargy subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Memory impairment subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Migraine subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Paraesthesia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Parosmia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Poor quality sleep			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Sciatica			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Somnolence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Tension headache			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Haemolysis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Haemolytic anaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Lymph node pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Lymphadenopathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
Tinnitus			

subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	
occurrences (all)	1	0	
Vertigo			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Eye pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Ocular discomfort			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Pinguecula			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Vision blurred			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Visual impairment			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Abdominal distension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Abdominal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Abdominal pain upper			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Aphthous ulcer			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Constipation			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	
occurrences (all)	1	0	
Dental caries			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Diarrhoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Diverticulum			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Dry mouth			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Dyspepsia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Faeces soft			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Flatulence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Frequent bowel movements			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Gastritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Gastrooesophageal reflux disease			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Hiatus hernia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Infrequent bowel movements			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Irritable bowel syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Lip dry			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Oral pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Paraesthesia oral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Salivary hypersecretion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Tongue ulceration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	
occurrences (all)	1	0	

Actinic keratosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Alopecia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Dermatitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Dermatitis contact			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Dry skin			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Ecchymosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Eczema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Erythema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Hyperhidrosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Hyperkeratosis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Macule			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Night sweats			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	

Photosensitivity reaction subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Pruritus subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Rash subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Rash erythematous subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Rash macular subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 4 (25.00%) 1	
Rash maculo-papular subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Skin discolouration subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Skin lesion subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Urticaria subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Renal and urinary disorders			
Nephrolithiasis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Nephropathy subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Renal cyst			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Ankylosing spondylitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Arthralgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Back pain			
subjects affected / exposed	1 / 7 (14.29%)	1 / 4 (25.00%)	
occurrences (all)	1	1	
Fibromyalgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Groin pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Intervertebral disc degeneration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Joint swelling			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Muscle spasms			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal stiffness			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Myalgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Neck pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Pain in extremity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Plantar fasciitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Rhabdomyolysis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Bronchitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Cellulitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Cystitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Ear infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	

Genital herpes			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Gingivitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Herpes simplex			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Hordeolum			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Infected dermal cyst			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Influenza			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Oral herpes			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Otitis media			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Paronychia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Periodontitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	

Pharyngitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Pharyngitis streptococcal			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Rhinitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Sinusitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Tooth abscess			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Tooth infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Viral infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	

Wound infection staphylococcal subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Gout subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Hyperamylasaemia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Hyperlipasaemia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Hyperlipidaemia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Hypokalaemia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Increased appetite subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Vitamin D deficiency subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 December 2014	Amendment 1: major revisions include changes to dosage and number of treatment arms
03 June 2015	Amendment 2: major revisions include changes to dosage, number of treatment arms, and sample sizes
23 September 2015	Amendment 3: major revisions include changes to the number of treatment arms, the durations of treatment to be studied, the number of participants per arm, the inclusion of ribavirin in some treatment arms, and the timing of initiation of each treatment arm.
16 February 2016	Amendment 4: major revisions include changes to the number of treatment arms
14 March 2016	Amendment 5: major revisions include changes to the assignment of participants to treatment arms
22 June 2016	Amendment 6: major revisions include changes to a long-term follow-up study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported