



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 GT1 and GT2 Infection

Summary

EudraCT number	2014-003304-73
Trial protocol	SE ES DE DK LT AT PL GB IT
Global end of trial date	12 December 2016

Results information

Result version number	v1 (current)
This version publication date	14 December 2017
First version publication date	14 December 2017

Trial information

Trial identification

Sponsor protocol code	3682-011
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02332707
WHO universal trial number (UTN)	-
Other trial identifiers	MK-3682-011: Merck Protocol Number

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	12 December 2016
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	12 December 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This is a randomized, three-part, open-label trial of grazoprevir (GZR; MK-5172) (100 mg) and uprifosbuvir (UPR; MK-3682) (300 mg or 450 mg), with either elbasvir (EBR; MK-8742) (50 mg) or ruzasvir (RZR; MK-8408) (60 mg), and with or without ribavirin (RBV), in treatment-naïve (TN) cirrhotic (C) or non-cirrhotic (NC) hepatitis C virus (HCV) participants with chronic HCV genotype (GT) 1 or GT2 infection. Part A will consist of 8 arms to evaluate the safety of dose combinations. In Part B, participants will take 2 GZR+UPR+RZR fixed dose combination (FDC) tablets once daily (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 UPR+GZR+RZR 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.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 January 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 18
Country: Number of subjects enrolled	Austria: 8
Country: Number of subjects enrolled	Canada: 31
Country: Number of subjects enrolled	Denmark: 26
Country: Number of subjects enrolled	France: 16
Country: Number of subjects enrolled	Germany: 12
Country: Number of subjects enrolled	Israel: 39
Country: Number of subjects enrolled	Italy: 12
Country: Number of subjects enrolled	Lithuania: 16
Country: Number of subjects enrolled	New Zealand: 9
Country: Number of subjects enrolled	Poland: 17
Country: Number of subjects enrolled	Spain: 63
Country: Number of subjects enrolled	Sweden: 15
Country: Number of subjects enrolled	United Kingdom: 8

Country: Number of subjects enrolled	United States: 152
Worldwide total number of subjects	442
EEA total number of subjects	193

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)	373
From 65 to 84 years	68
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

This trial was conducted at 95 study sites in Asia, the European Union, and North America.

Pre-assignment

Screening details:

The "Number Started" row reflects the number of randomized participants who received study treatment. A total of 443 participants were randomized but 1 participant withdrew consent prior to receiving any study treatment.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	A1: GT1 NC GZR+UPR+EBR (8 weeks)

Arm description:

In Part A, HCV genotype GT1-infected NC participants took GZR 100 mg + UPR 300 mg + EBR 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:

One GZR 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:

Two or 3 UPR 150 mg (300 mg or 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	Tablet
Routes of administration	Oral use

Dosage and administration details:

One EBR 50 mg tablet taken q.d. by mouth.

Arm title	A2: GT1 NC GZR+UPR+RZR (8 weeks)
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Arm description:

In Part A, HCV GT1-infected NC participants took GZR 100 mg + UPR 300 mg + ruzasvir (RZR) 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:

One GZR 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:

Two or 3 UPR 150 mg (300 mg or 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	Capsule
Routes of administration	Oral use

Dosage and administration details:

Six RZR 10 mg (60 mg total daily dose) capsules taken q.d. by mouth.

Arm title	A3: GT2 NC GZR+UPR+EBR (8 weeks)
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Arm description:

In Part A, HCV GT2-infected NC participants took GZR 100 mg + UPR 300 mg + EBR 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:

One GZR 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:

Two or 3 UPR 150 mg (300 mg or 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	Tablet
Routes of administration	Oral use

Dosage and administration details:

One EBR 50 mg tablet taken q.d. by mouth.

Arm title	A4: GT2 NC GZR+UPR+RZR (8 weeks)
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Arm description:

In Part A, HCV GT2-infected NC participants took GZR 100 mg + UPR 300 mg + RZR 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:

One GZR 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:

Two or 3 UPR 150 mg (300 mg or 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	Capsule
Routes of administration	Oral use

Dosage and administration details:

Six RZR 10 mg (60 mg total daily dose) capsules taken q.d. by mouth.

Arm title	A5: GT1 NC GZR+UPR+EBR (8 weeks)
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Arm description:

In Part A, HCV GT1-infected NC participants took GZR 100 mg + UPR 450 mg + EBR 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:

One GZR 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:

Two or 3 UPR 150 mg (300 mg or 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	Tablet
Routes of administration	Oral use

Dosage and administration details:

One EBR 50 mg tablet taken q.d. by mouth.

Arm title	A6: GT1 NC GZR+UPR+RZR (8 weeks)
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Arm description:

In Part A, HCV GT1-infected NC participants took GZR 100 mg + UPR 450 mg + RZR 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:

One GZR 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:

Two or 3 UPR 150 mg (300 mg or 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	Capsule
Routes of administration	Oral use

Dosage and administration details:

Six RZR 10 mg (60 mg total daily dose) capsules taken q.d. by mouth.

Arm title	A7: GT2 NC GZR+UPR+EBR (8 weeks)
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Arm description:

In Part A, HCV GT2-infected NC participants took GZR 100 mg + UPR 450 mg + EBR 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:

One GZR 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:

Two or 3 UPR 150 mg (300 mg or 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	Tablet
Routes of administration	Oral use

Dosage and administration details:

One EBR 50 mg tablet taken q.d. by mouth.

Arm title	A8: GT2 NC GZR+UPR+RZR (8 weeks)
Arm description: In Part A, HCV GT2-infected NC participants took GZR 100 mg + UPR 450 mg + RZR 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: One GZR 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: Two or 3 UPR 150 mg (300 mg or 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	Capsule
Routes of administration	Oral use
Dosage and administration details: Six RZR 10 mg (60 mg total daily dose) capsules taken q.d. by mouth.	
Arm title	B9: GT1 NC GZR+UPR+RZR (12 weeks)
Arm description: In Part B, HCV GT1-infected NC participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 12 weeks.	
Arm type	Experimental
Investigational medicinal product name	Grazoprevir (+) Uprifosbuvir (+) Ruzasvir FDC
Investigational medicinal product code	
Other name	MK-3682B
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: Two FDC tablets, each containing GZR 50 mg + UPR 225 mg + RZR 30 mg, taken q.d. by mouth.	
Arm title	B10: GT2 NC GZR+UPR+RZR (8 weeks) + RBV
Arm description: In Part B, HCV GT2-infected NC participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 8 weeks. Participants also took RBV b.i.d. at a total daily dose of 800-1600 mg based on body weight.	
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: RBV 200 mg capsules taken b.i.d. at a total daily dose of 800-1400 mg based on participant body weight.	

Investigational medicinal product name	Grazoprevir (+) Uprifosbuvir (+) Ruzasvir FDC
Investigational medicinal product code	
Other name	MK-3682B
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Two FDC tablets, each containing GZR 50 mg + UPR 225 mg + RZR 30 mg, taken q.d. by mouth.	
Arm title	B11: GT2 NC GZR+UPR+RZR (12 weeks)
Arm description:	
In Part B, HCV GT2-infected NC participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 12 weeks.	
Arm type	Experimental
Investigational medicinal product name	Grazoprevir (+) Uprifosbuvir (+) Ruzasvir FDC
Investigational medicinal product code	
Other name	MK-3682B
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Two FDC tablets, each containing GZR 50 mg + UPR 225 mg + RZR 30 mg, taken q.d. by mouth.	
Arm title	B12: GT1 C GZR+UPR+RZR (8 weeks)
Arm description:	
In Part B, HCV GT1-infected C participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 8 weeks.	
Arm type	Experimental
Investigational medicinal product name	Grazoprevir (+) Uprifosbuvir (+) Ruzasvir FDC
Investigational medicinal product code	
Other name	MK-3682B
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Two FDC tablets, each containing GZR 50 mg + UPR 225 mg + RZR 30 mg, taken q.d. by mouth.	
Arm title	B13: GT1 C GZR+UPR+RZR (12 weeks)
Arm description:	
In Part B, HCV GT1-infected C participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 12 weeks.	
Arm type	Experimental
Investigational medicinal product name	Grazoprevir (+) Uprifosbuvir (+) Ruzasvir FDC
Investigational medicinal product code	
Other name	MK-3682B
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Two FDC tablets, each containing GZR 50 mg + UPR 225 mg + RZR 30 mg, taken q.d. by mouth.	
Arm title	B14: GT2 C GZR+UPR+RZR (12 weeks)
Arm description:	
In Part B, HCV GT2-infected C participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 12 weeks.	
Arm type	Experimental

Investigational medicinal product name	Grazoprevir (+) Uprifosbuvir (+) Ruzasvir FDC
Investigational medicinal product code	
Other name	MK-3682B
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Two FDC tablets, each containing GZR 50 mg + UPR 225 mg + RZR 30 mg, taken q.d. by mouth.

Arm title	B15: GT2 C GZR+UPR+RZR (12 weeks) + RBV
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Arm description:

In Part B, HCV GT2-infected C participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 12 weeks. Participants also took RBV b.i.d. at a total daily dose of 800-1600 mg based on body weight.

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:

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

Investigational medicinal product name	Grazoprevir (+) Uprifosbuvir (+) Ruzasvir FDC
Investigational medicinal product code	
Other name	MK-3682B
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Two FDC tablets, each containing GZR 50 mg + UPR 225 mg + RZR 30 mg, taken q.d. by mouth.

Arm title	B16: GT2 C GZR+UPR+RZR (16 weeks)
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Arm description:

In Part B, HCV GT2-infected C participants took 2 FDC tablets containing UPR 225 mg + GZR 50 mg + RZR 30 mg per tablet q.d. by mouth for 16 weeks.

Arm type	Experimental
Investigational medicinal product name	Grazoprevir (+) Uprifosbuvir (+) Ruzasvir FDC
Investigational medicinal product code	
Other name	MK-3682B
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Two FDC tablets, each containing GZR 50 mg + UPR 225 mg + RZR 30 mg, taken q.d. by mouth.

Arm title	B6: GT1 NC GZR+UPR+RZR (8 weeks)
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Arm description:

In Part B, HCV GT1-infected NC participants took 2 FDC tablets containing UPR 225 mg + GZR 50 mg + RZR 30 mg per tablet q.d. by mouth for 8 weeks.

Arm type	Experimental
Investigational medicinal product name	Grazoprevir (+) Uprifosbuvir (+) Ruzasvir FDC
Investigational medicinal product code	
Other name	MK-3682B
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Two FDC tablets, each containing GZR 50 mg + UPR 225 mg + RZR 30 mg, taken q.d. by mouth.

Arm title	B8: GT2 NC GZR+UPR+RZR (8 weeks)
Arm description:	
In Part B, HCV GT2-infected NC participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 8 weeks.	
Arm type	Experimental
Investigational medicinal product name	Grazoprevir (+) Uprifosbuvir (+) Ruzasvir FDC
Investigational medicinal product code	
Other name	MK-3682B
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Two FDC tablets, each containing GZR 50 mg + UPR 225 mg + RZR 30 mg, taken q.d. by mouth.

Number of subjects in period 1	A1: GT1 NC GZR+UPR+EBR (8 weeks)	A2: GT1 NC GZR+UPR+RZR (8 weeks)	A3: GT2 NC GZR+UPR+EBR (8 weeks)
Started	23	24	16
Completed	23	24	15
Not completed	0	0	1
Consent withdrawn by subject	-	-	1
Physician decision	-	-	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	A4: GT2 NC GZR+UPR+RZR (8 weeks)	A5: GT1 NC GZR+UPR+EBR (8 weeks)	A6: GT1 NC GZR+UPR+RZR (8 weeks)
Started	14	23	23
Completed	13	23	22
Not completed	1	0	1
Consent withdrawn by subject	-	-	-
Physician decision	1	-	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	-	-	1

Number of subjects in period 1	A7: GT2 NC GZR+UPR+EBR (8 weeks)	A8: GT2 NC GZR+UPR+RZR (8 weeks)	B9: GT1 NC GZR+UPR+RZR (12 weeks)
Started	15	16	48
Completed	15	16	48
Not completed	0	0	0
Consent withdrawn by subject	-	-	-
Physician decision	-	-	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	B10: GT2 NC GZR+UPR+RZR (8 weeks) + RBV	B11: GT2 NC GZR+UPR+RZR (12 weeks)	B12: GT1 C GZR+UPR+RZR (8 weeks)
Started	31	31	35
Completed	28	29	35
Not completed	3	2	0
Consent withdrawn by subject	3	-	-
Physician decision	-	-	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	-	2	-

Number of subjects in period 1	B13: GT1 C GZR+UPR+RZR (12 weeks)	B14: GT2 C GZR+UPR+RZR (12 weeks)	B15: GT2 C GZR+UPR+RZR (12 weeks) + RBV
Started	40	15	16
Completed	35	15	16
Not completed	5	0	0
Consent withdrawn by subject	-	-	-
Physician decision	1	-	-
Adverse event, non-fatal	1	-	-
Lost to follow-up	3	-	-

Number of subjects in period 1	B16: GT2 C GZR+UPR+RZR (16 weeks)	B6: GT1 NC GZR+UPR+RZR (8 weeks)	B8: GT2 NC GZR+UPR+RZR (8 weeks)
Started	26	30	16
Completed	26	30	16
Not completed	0	0	0
Consent withdrawn by subject	-	-	-
Physician decision	-	-	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	-	-	-

Baseline characteristics

Reporting groups

Reporting group title	A1: GT1 NC GZR+UPR+EBR (8 weeks)
Reporting group description: In Part A, HCV genotype GT1-infected NC participants took GZR 100 mg + UPR 300 mg + EBR 50 mg q.d. by mouth for 8 weeks.	
Reporting group title	A2: GT1 NC GZR+UPR+RZR (8 weeks)
Reporting group description: In Part A, HCV GT1-infected NC participants took GZR 100 mg + UPR 300 mg + ruzasvir (RZR) 60 mg q.d. by mouth for 8 weeks.	
Reporting group title	A3: GT2 NC GZR+UPR+EBR (8 weeks)
Reporting group description: In Part A, HCV GT2-infected NC participants took GZR 100 mg + UPR 300 mg + EBR 50 mg q.d. by mouth for 8 weeks.	
Reporting group title	A4: GT2 NC GZR+UPR+RZR (8 weeks)
Reporting group description: In Part A, HCV GT2-infected NC participants took GZR 100 mg + UPR 300 mg + RZR 60 mg q.d. by mouth for 8 weeks.	
Reporting group title	A5: GT1 NC GZR+UPR+EBR (8 weeks)
Reporting group description: In Part A, HCV GT1-infected NC participants took GZR 100 mg + UPR 450 mg + EBR 50 mg q.d. by mouth for 8 weeks.	
Reporting group title	A6: GT1 NC GZR+UPR+RZR (8 weeks)
Reporting group description: In Part A, HCV GT1-infected NC participants took GZR 100 mg + UPR 450 mg + RZR 60 mg q.d. by mouth for 8 weeks.	
Reporting group title	A7: GT2 NC GZR+UPR+EBR (8 weeks)
Reporting group description: In Part A, HCV GT2-infected NC participants took GZR 100 mg + UPR 450 mg + EBR 50 mg q.d. by mouth for 8 weeks.	
Reporting group title	A8: GT2 NC GZR+UPR+RZR (8 weeks)
Reporting group description: In Part A, HCV GT2-infected NC participants took GZR 100 mg + UPR 450 mg + RZR 60 mg q.d. by mouth for 8 weeks.	
Reporting group title	B9: GT1 NC GZR+UPR+RZR (12 weeks)
Reporting group description: In Part B, HCV GT1-infected NC participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 12 weeks.	
Reporting group title	B10: GT2 NC GZR+UPR+RZR (8 weeks) + RBV
Reporting group description: In Part B, HCV GT2-infected NC participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 8 weeks. Participants also took RBV b.i.d. at a total daily dose of 800-1600 mg based on body weight.	
Reporting group title	B11: GT2 NC GZR+UPR+RZR (12 weeks)
Reporting group description: In Part B, HCV GT2-infected NC participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 12 weeks.	
Reporting group title	B12: GT1 C GZR+UPR+RZR (8 weeks)
Reporting group description: In Part B, HCV GT1-infected C participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 8 weeks.	
Reporting group title	B13: GT1 C GZR+UPR+RZR (12 weeks)
Reporting group description: In Part B, HCV GT1-infected C participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg +	

RZR 30 mg per tablet q.d. by mouth for 12 weeks.

Reporting group title	B14: GT2 C GZR+UPR+RZR (12 weeks)
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Reporting group description:

In Part B, HCV GT2-infected C participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 12 weeks.

Reporting group title	B15: GT2 C GZR+UPR+RZR (12 weeks) + RBV
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Reporting group description:

In Part B, HCV GT2-infected C participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 12 weeks. Participants also took RBV b.i.d. at a total daily dose of 800-1600 mg based on body weight.

Reporting group title	B16: GT2 C GZR+UPR+RZR (16 weeks)
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Reporting group description:

In Part B, HCV GT2-infected C participants took 2 FDC tablets containing UPR 225 mg + GZR 50 mg + RZR 30 mg per tablet q.d. by mouth for 16 weeks.

Reporting group title	B6: GT1 NC GZR+UPR+RZR (8 weeks)
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Reporting group description:

In Part B, HCV GT1-infected NC participants took 2 FDC tablets containing UPR 225 mg + GZR 50 mg + RZR 30 mg per tablet q.d. by mouth for 8 weeks.

Reporting group title	B8: GT2 NC GZR+UPR+RZR (8 weeks)
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Reporting group description:

In Part B, HCV GT2-infected NC participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 8 weeks.

Reporting group values	A1: GT1 NC GZR+UPR+EBR (8 weeks)	A2: GT1 NC GZR+UPR+RZR (8 weeks)	A3: GT2 NC GZR+UPR+EBR (8 weeks)
Number of subjects	23	24	16
Age categorical Units: Subjects			

Age Continuous Units: Years			
arithmetic mean	50.2	45.0	49.4
standard deviation	± 13.5	± 14.5	± 15.8
Gender, Male/Female Units: Subjects			
Female	10	13	7
Male	13	11	9

Reporting group values	A4: GT2 NC GZR+UPR+RZR (8 weeks)	A5: GT1 NC GZR+UPR+EBR (8 weeks)	A6: GT1 NC GZR+UPR+RZR (8 weeks)
Number of subjects	14	23	23
Age categorical Units: Subjects			

Age Continuous Units: Years			
arithmetic mean	52.6	49.0	46.7
standard deviation	± 11.6	± 11.2	± 13.9
Gender, Male/Female Units: Subjects			
Female	5	14	9

Male	9	9	14
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Reporting group values	A7: GT2 NC GZR+UPR+EBR (8 weeks)	A8: GT2 NC GZR+UPR+RZR (8 weeks)	B9: GT1 NC GZR+UPR+RZR (12 weeks)
Number of subjects	15	16	48
Age categorical Units: Subjects			

Age Continuous Units: Years			
arithmetic mean	52.9	48.3	48.8
standard deviation	± 12.1	± 8.8	± 13.9
Gender, Male/Female Units: Subjects			
Female	9	8	21
Male	6	8	27

Reporting group values	B10: GT2 NC GZR+UPR+RZR (8 weeks) + RBV	B11: GT2 NC GZR+UPR+RZR (12 weeks)	B12: GT1 C GZR+UPR+RZR (8 weeks)
Number of subjects	31	31	35
Age categorical Units: Subjects			

Age Continuous Units: Years			
arithmetic mean	49.8	55.6	58.8
standard deviation	± 13.0	± 14.4	± 9.6
Gender, Male/Female Units: Subjects			
Female	16	16	14
Male	15	15	21

Reporting group values	B13: GT1 C GZR+UPR+RZR (12 weeks)	B14: GT2 C GZR+UPR+RZR (12 weeks)	B15: GT2 C GZR+UPR+RZR (12 weeks) + RBV
Number of subjects	40	15	16
Age categorical Units: Subjects			

Age Continuous Units: Years			
arithmetic mean	56.9	61.8	59.8
standard deviation	± 11.1	± 6.8	± 8.0
Gender, Male/Female Units: Subjects			
Female	11	3	4
Male	29	12	12

Reporting group values	B16: GT2 C GZR+UPR+RZR (16 weeks)	B6: GT1 NC GZR+UPR+RZR (8 weeks)	B8: GT2 NC GZR+UPR+RZR (8 weeks)
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	weeks)	weeks)	weeks)
Number of subjects	26	30	16
Age categorical Units: Subjects			

Age Continuous Units: Years arithmetic mean standard deviation	64.0 ± 9.3	47.4 ± 11.7	51.4 ± 10.8
Gender, Male/Female Units: Subjects			
Female	9	14	9
Male	17	16	7

Reporting group values	Total		
Number of subjects	442		
Age categorical Units: Subjects			

Age Continuous Units: Years arithmetic mean standard deviation	-		
Gender, Male/Female Units: Subjects			
Female	192		
Male	250		

End points

End points reporting groups

Reporting group title	A1: GT1 NC GZR+UPR+EBR (8 weeks)
Reporting group description: In Part A, HCV genotype GT1-infected NC participants took GZR 100 mg + UPR 300 mg + EBR 50 mg q.d. by mouth for 8 weeks.	
Reporting group title	A2: GT1 NC GZR+UPR+RZR (8 weeks)
Reporting group description: In Part A, HCV GT1-infected NC participants took GZR 100 mg + UPR 300 mg + ruzasvir (RZR) 60 mg q.d. by mouth for 8 weeks.	
Reporting group title	A3: GT2 NC GZR+UPR+EBR (8 weeks)
Reporting group description: In Part A, HCV GT2-infected NC participants took GZR 100 mg + UPR 300 mg + EBR 50 mg q.d. by mouth for 8 weeks.	
Reporting group title	A4: GT2 NC GZR+UPR+RZR (8 weeks)
Reporting group description: In Part A, HCV GT2-infected NC participants took GZR 100 mg + UPR 300 mg + RZR 60 mg q.d. by mouth for 8 weeks.	
Reporting group title	A5: GT1 NC GZR+UPR+EBR (8 weeks)
Reporting group description: In Part A, HCV GT1-infected NC participants took GZR 100 mg + UPR 450 mg + EBR 50 mg q.d. by mouth for 8 weeks.	
Reporting group title	A6: GT1 NC GZR+UPR+RZR (8 weeks)
Reporting group description: In Part A, HCV GT1-infected NC participants took GZR 100 mg + UPR 450 mg + RZR 60 mg q.d. by mouth for 8 weeks.	
Reporting group title	A7: GT2 NC GZR+UPR+EBR (8 weeks)
Reporting group description: In Part A, HCV GT2-infected NC participants took GZR 100 mg + UPR 450 mg + EBR 50 mg q.d. by mouth for 8 weeks.	
Reporting group title	A8: GT2 NC GZR+UPR+RZR (8 weeks)
Reporting group description: In Part A, HCV GT2-infected NC participants took GZR 100 mg + UPR 450 mg + RZR 60 mg q.d. by mouth for 8 weeks.	
Reporting group title	B9: GT1 NC GZR+UPR+RZR (12 weeks)
Reporting group description: In Part B, HCV GT1-infected NC participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 12 weeks.	
Reporting group title	B10: GT2 NC GZR+UPR+RZR (8 weeks) + RBV
Reporting group description: In Part B, HCV GT2-infected NC participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 8 weeks. Participants also took RBV b.i.d. at a total daily dose of 800-1600 mg based on body weight.	
Reporting group title	B11: GT2 NC GZR+UPR+RZR (12 weeks)
Reporting group description: In Part B, HCV GT2-infected NC participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 12 weeks.	
Reporting group title	B12: GT1 C GZR+UPR+RZR (8 weeks)
Reporting group description: In Part B, HCV GT1-infected C participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 8 weeks.	
Reporting group title	B13: GT1 C GZR+UPR+RZR (12 weeks)
Reporting group description: In Part B, HCV GT1-infected C participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg +	

RZR 30 mg per tablet q.d. by mouth for 12 weeks.

Reporting group title	B14: GT2 C GZR+UPR+RZR (12 weeks)
Reporting group description:	
In Part B, HCV GT2-infected C participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 12 weeks.	
Reporting group title	B15: GT2 C GZR+UPR+RZR (12 weeks) + RBV
Reporting group description:	
In Part B, HCV GT2-infected C participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 12 weeks. Participants also took RBV b.i.d. at a total daily dose of 800-1600 mg based on body weight.	
Reporting group title	B16: GT2 C GZR+UPR+RZR (16 weeks)
Reporting group description:	
In Part B, HCV GT2-infected C participants took 2 FDC tablets containing UPR 225 mg + GZR 50 mg + RZR 30 mg per tablet q.d. by mouth for 16 weeks.	
Reporting group title	B6: GT1 NC GZR+UPR+RZR (8 weeks)
Reporting group description:	
In Part B, HCV GT1-infected NC participants took 2 FDC tablets containing UPR 225 mg + GZR 50 mg + RZR 30 mg per tablet q.d. by mouth for 8 weeks.	
Reporting group title	B8: GT2 NC GZR+UPR+RZR (8 weeks)
Reporting group description:	
In Part B, HCV GT2-infected NC participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 8 weeks.	

Primary: Percentage of participants achieving sustained virologic response 12 weeks after completing treatment (SVR12)

End point title	Percentage of participants achieving sustained virologic response 12 weeks after completing treatment (SVR12) ^[1]
End point description:	
The percentage of participants with Hepatitis C virus (HCV) ribonucleic acid (RNA) < Lower Limit of Quantification (LLOQ) 12 weeks after completing treatment (i.e., SVR12) in each arm was determined. Plasma levels of HCV RNA levels were measured using the Roche COBAS® AmpliPrep/COBAS® TaqMan® HCV Test, v2.0 assay, which has a LLOQ of 15 IU/mL. The analysis population includes all randomized participants who received at least 1 dose of study drug and had SVR12 results available.	
End point type	Primary
End point timeframe:	
Up to 28 weeks	

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: Per protocol, only descriptive statistics are presented.

End point values	A1: GT1 NC GZR+UPR+EBR (8 weeks)	A2: GT1 NC GZR+UPR+RZR (8 weeks)	A3: GT2 NC GZR+UPR+EBR (8 weeks)	A4: GT2 NC GZR+UPR+RZR (8 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	24	16	14
Units: Percentage of Participants				
number (confidence interval 95%)	100.0 (85.2 to 100.0)	100.0 (85.8 to 100.0)	68.8 (41.3 to 89.0)	71.4 (41.9 to 91.6)

End point values	A5: GT1 NC GZR+UPR+EBR	A6: GT1 NC GZR+UPR+RZR	A7: GT2 NC GZR+UPR+EBR	A8: GT2 NC GZR+UPR+RZR
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	(8 weeks)	R (8 weeks)	(8 weeks)	R (8 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	23	15	16
Units: Percentage of Participants				
number (confidence interval 95%)	100.0 (85.2 to 100.0)	91.3 (72.0 to 98.9)	60.0 (32.3 to 83.7)	93.8 (69.8 to 99.8)

End point values	B9: GT1 NC GZR+UPR+RZ R (12 weeks)	B10: GT2 NC GZR+UPR+RZ R (8 weeks) + RBV	B11: GT2 NC GZR+UPR+RZ R (12 weeks)	B12: GT1 C GZR+UPR+RZ R (8 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	30	30	35
Units: Percentage of Participants				
number (confidence interval 95%)	100.0 (92.6 to 100.0)	83.3 (65.3 to 94.4)	100.0 (88.4 to 100.0)	97.1 (85.1 to 99.9)

End point values	B13: GT1 C GZR+UPR+RZ R (12 weeks)	B14: GT2 C GZR+UPR+RZ R (12 weeks)	B15: GT2 C GZR+UPR+RZ R (12 weeks) + RBV	B16: GT2 C GZR+UPR+RZ R (16 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	15	16	25
Units: Percentage of Participants				
number (confidence interval 95%)	100.0 (91.0 to 100.0)	100.0 (78.2 to 100.0)	100.0 (79.4 to 100.0)	100.0 (86.3 to 100.0)

End point values	B6: GT1 NC GZR+UPR+RZ R (8 weeks)	B8: GT2 NC GZR+UPR+RZ R (8 weeks)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	16		
Units: Percentage of Participants				
number (confidence interval 95%)	100.0 (88.4 to 100.0)	87.5 (61.7 to 98.4)		

Statistical analyses

No statistical analyses for this end point

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

End point title	Percentage of participants experiencing an adverse event
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End point description:

An AE is defined as any untoward medical occurrence in a participant administered a pharmaceutical

product and which does not necessarily have to have a causal relationship with this treatment. The analysis population includes all randomized participants who received at least 1 dose of study drug.

End point type	Primary
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End point timeframe:

Up to 18 weeks

Notes:

[2] - 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: Per protocol, only descriptive statistics are presented.

End point values	A1: GT1 NC GZR+UPR+EBR (8 weeks)	A2: GT1 NC GZR+UPR+RZ R (8 weeks)	A3: GT2 NC GZR+UPR+EBR (8 weeks)	A4: GT2 NC GZR+UPR+RZ R (8 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	24	16	14
Units: Percentage of Participants				
number (not applicable)	60.9	83.3	56.3	71.4

End point values	A5: GT1 NC GZR+UPR+EBR (8 weeks)	A6: GT1 NC GZR+UPR+RZ R (8 weeks)	A7: GT2 NC GZR+UPR+EBR (8 weeks)	A8: GT2 NC GZR+UPR+RZ R (8 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	23	15	16
Units: Percentage of Participants				
number (not applicable)	73.9	60.9	62.3	86.7

End point values	B9: GT1 NC GZR+UPR+RZ R (12 weeks)	B10: GT2 NC GZR+UPR+RZ R (8 weeks) + RBV	B11: GT2 NC GZR+UPR+RZ R (12 weeks)	B12: GT1 C GZR+UPR+RZ R (8 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	31	31	35
Units: Percentage of Participants				
number (not applicable)	68.8	72.9	80.6	71.0

End point values	B13: GT1 C GZR+UPR+RZ R (12 weeks)	B14: GT2 C GZR+UPR+RZ R (12 weeks)	B15: GT2 C GZR+UPR+RZ R (12 weeks) + RBV	B16: GT2 C GZR+UPR+RZ R (16 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	15	16	26
Units: Percentage of Participants				
number (not applicable)	57.1	72.5	53.3	81.3

End point values	B6: GT1 NC	B8: GT2 NC		
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	GZR+UPR+RZ R (8 weeks)	GZR+UPR+RZ R (8 weeks)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	16		
Units: Percentage of Participants				
number (not applicable)	69.2	75.0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of participants discontinuing from study treatment due to an AE

End point title	Percentage of participants discontinuing from study treatment due to an AE ^[3]
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End point description:

An AE is defined as any untoward medical occurrence in a participant administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment. The analysis population includes all randomized participants who received at least 1 dose of study drug.

End point type	Primary
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End point timeframe:

Up to 16 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: Per protocol, only descriptive statistics are presented.

End point values	A1: GT1 NC GZR+UPR+EBR (8 weeks)	A2: GT1 NC GZR+UPR+RZ R (8 weeks)	A3: GT2 NC GZR+UPR+EBR (8 weeks)	A4: GT2 NC GZR+UPR+RZ R (8 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	24	16	14
Units: Percentage of Participants				
number (not applicable)	0	0	0	0

End point values	A5: GT1 NC GZR+UPR+EBR (8 weeks)	A6: GT1 NC GZR+UPR+RZ R (8 weeks)	A7: GT2 NC GZR+UPR+EBR (8 weeks)	A8: GT2 NC GZR+UPR+RZ R (8 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	23	15	16
Units: Percentage of Participants				
number (not applicable)	0	0	0	0

End point values	B9: GT1 NC GZR+UPR+RZ R (12 weeks)	B10: GT2 NC GZR+UPR+RZ R (8 weeks) + RBV	B11: GT2 NC GZR+UPR+RZ R (12 weeks)	B12: GT1 C GZR+UPR+RZ R (8 weeks)
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	31	31	35
Units: Percentage of Participants				
number (not applicable)	0	6.5	0	0

End point values	B13: GT1 C GZR+UPR+RZ R (12 weeks)	B14: GT2 C GZR+UPR+RZ R (12 weeks)	B15: GT2 C GZR+UPR+RZ R (12 weeks) + RBV	B16: GT2 C GZR+UPR+RZ R (16 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	15	16	26
Units: Percentage of Participants				
number (not applicable)	2.5	0	12.5	0

End point values	B6: GT1 NC GZR+UPR+RZ R (8 weeks)	B8: GT2 NC GZR+UPR+RZ R (8 weeks)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	16		
Units: Percentage of Participants				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants achieving Sustained Virologic Response 24 weeks after ending study treatment (SVR24)

End point title	Percentage of participants achieving Sustained Virologic Response 24 weeks after ending study treatment (SVR24)
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End point description:

The percentage of participants with HCV RNA < LLoQ 24 weeks after completing treatment (i.e., SVR24) in each arm was determined. Plasma levels of HCV RNA levels were measured using the Roche COBAS® AmpliPrep/COBAS® TaqMan® HCV Test, v2.0 assay, which has a LLoQ of 15 IU/mL. The analysis population includes all randomized participants who received at least 1 dose of study drug and had SVR24 results available are included.

End point type	Secondary
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End point timeframe:

Up to 40 weeks

End point values	A1: GT1 NC GZR+UPR+EBR (8 weeks)	A2: GT1 NC GZR+UPR+RZ R (8 weeks)	A3: GT2 NC GZR+UPR+EBR (8 weeks)	A4: GT2 NC GZR+UPR+RZ R (8 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	24	16	14
Units: Percentage of Participants				
number (confidence interval 95%)	100.0 (85.2 to 100.0)	100.0 (85.8 to 100.0)	68.8 (41.3 to 89.0)	71.4 (41.9 to 91.6)

End point values	A5: GT1 NC GZR+UPR+EBR (8 weeks)	A6: GT1 NC GZR+UPR+RZ R (8 weeks)	A7: GT2 NC GZR+UPR+EBR (8 weeks)	A8: GT2 NC GZR+UPR+RZ R (8 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	22	15	16
Units: Percentage of Participants				
number (confidence interval 95%)	100.0 (85.2 to 100.0)	90.9 (70.8 to 98.9)	60.0 (32.3 to 83.7)	93.8 (69.8 to 99.8)

End point values	B9: GT1 NC GZR+UPR+RZ R (12 weeks)	B10: GT2 NC GZR+UPR+RZ R (8 weeks) + RBV	B11: GT2 NC GZR+UPR+RZ R (12 weeks)	B12: GT1 C GZR+UPR+RZ R (8 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	30	29	35
Units: Percentage of Participants				
number (confidence interval 95%)	100.0 (92.6 to 100.0)	83.3 (65.3 to 94.4)	100.0 (88.1 to 100.0)	97.1 (85.1 to 99.9)

End point values	B13: GT1 C GZR+UPR+RZ R (12 weeks)	B14: GT2 C GZR+UPR+RZ R (12 weeks)	B15: GT2 C GZR+UPR+RZ R (12 weeks) + RBV	B16: GT2 C GZR+UPR+RZ R (16 weeks)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	15	16	26
Units: Percentage of Participants				
number (confidence interval 95%)	100.0 (90.1 to 100.0)	100.0 (78.2 to 100.0)	100.0 (79.4 to 100.0)	100.0 (86.3 to 100.0)

End point values	B6: GT1 NC GZR+UPR+RZ R (8 weeks)	B8: GT2 NC GZR+UPR+RZ R (8 weeks)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	16		
Units: Percentage of Participants				
number (confidence interval 95%)	100.0 (88.4 to 100.0)	87.5 (61.7 to 98.4)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 18 weeks (14 days after completing all study therapy)

Adverse event reporting additional description:

All participants who received at least 1 dose of study treatment are included.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	19.1
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Reporting groups

Reporting group title	A2: GT1 NC GZR+UPR+RZR (8 weeks)
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Reporting group description:

In Part A, HCV GT1-infected NC participants took GZR 100 mg + UPR 300 mg + RZR 60 mg q.d. by mouth for 8 weeks.

Reporting group title	A1: GT1 NC GZR+UPR+EBR (8 weeks)
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Reporting group description:

In Part A, HCV GT1-infected NC participants took GZR 100 mg + UPR 300 mg + EBR 50 mg q.d. by mouth for 8 weeks.

Reporting group title	A3: GT2 NC GZR+UPR+EBR (8 weeks)
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Reporting group description:

In Part A, HCV GT2-infected NC participants took GZR 100 mg + UPR 300 mg + EBR 50 mg q.d. by mouth for 8 weeks.

Reporting group title	A4: GT2 NC GZR+UPR+RZR (8 weeks)
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Reporting group description:

In Part A, HCV GT2-infected NC participants took GZR 100 mg + UPR 300 mg + RZR 60 mg q.d. by mouth for 8 weeks.

Reporting group title	A5: GT1 NC GZR+UPR+EBR (8 weeks)
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Reporting group description:

In Part A, HCV GT1-infected NC participants took GZR 100 mg + UPR 450 mg + EBR 50 mg q.d. by mouth for 8 weeks.

Reporting group title	A6: GT1 NC GZR+UPR+RZR (8 weeks)
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Reporting group description:

In Part A, HCV GT1-infected NC participants took GZR 100 mg + UPR 450 mg + RZR 60 mg q.d. by mouth for 8 weeks.

Reporting group title	A8: GT2 NC GZR+UPR+RZR (8 weeks)
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Reporting group description:

In Part A, HCV GT2-infected NC participants took GZR 100 mg + UPR 450 mg + RZR 60 mg q.d. by mouth for 8 weeks.

Reporting group title	A7: GT2 NC GZR+UPR+EBR (8 weeks)
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Reporting group description:

In Part A, HCV GT2-infected NC participants took GZR 100 mg + UPR 450 mg + EBR 50 mg q.d. by mouth for 8 weeks.

Reporting group title	B6: GT1 NC GZR+UPR+RVR (8 weeks)
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Reporting group description:

In Part B, HCV GT1-infected NC participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 8 weeks.

Reporting group title	B8: GT2 NC GZR+UPR+RZR (8 weeks)
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Reporting group description:

In Part B, HCV GT2-infected NC participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 8 weeks.

Reporting group title	B9: GT1 NC GZR+UPR+RZR (12 weeks)
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Reporting group description:

In Part B, HCV GT1-infected NC participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 12 weeks.

Reporting group title	B10: GT2 NC GZR+UPR+RZR (8 weeks) + RBV
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Reporting group description:

In Part B, HCV GT2-infected NC participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 8 weeks. Participants will also take RBV b.i.d. at a total daily dose of 800-1600 mg based on body weight.

Reporting group title	B11: GT2 NC GZR+UPR+RZR (12 weeks)
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Reporting group description:

In Part B, HCV GT2-infected NC participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 12 weeks.

Reporting group title	B12: GT1 C GZR+UPR+RZR (8 weeks)
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Reporting group description:

In Part B, HCV GT1-infected C participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 8 weeks.

Reporting group title	B13: GT1 C GZR+UPR+RZR (12 weeks)
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Reporting group description:

In Part B, HCV GT1-infected C participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 12 weeks.

Reporting group title	B14: GT2 C GZR+UPR+RZR (12 weeks)
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Reporting group description:

In Part B, HCV GT2-infected C participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 12 weeks.

Reporting group title	B15: GT2 C GZR+UPR+RZR (12 weeks) + RBV
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Reporting group description:

In Part B, HCV GT2-infected C participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 12 weeks. Participants will also take RBV b.i.d. at a total daily dose of 800-1600 mg based on body weight.

Reporting group title	B16: GT2 C GZR+UPR+RZRasvir (16 weeks)
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Reporting group description:

In Part B, HCV GT2-infected C participants took 2 FDC tablets containing GZR 50 mg + UPR 225 mg + RZR 30 mg per tablet q.d. by mouth for 16 weeks.

Serious adverse events	A2: GT1 NC GZR+UPR+RZR (8 weeks)	A1: GT1 NC GZR+UPR+EBR (8 weeks)	A3: GT2 NC GZR+UPR+EBR (8 weeks)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 24 (4.17%)	0 / 23 (0.00%)	1 / 16 (6.25%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			

subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Retinal artery occlusion			
subjects affected / exposed	1 / 24 (4.17%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
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			
Depression			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance-induced psychotic disorder			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
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			
Device related infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal cyst			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
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	A4: GT2 NC GZR+UPR+RZR (8 weeks)	A5: GT1 NC GZR+UPR+EBR (8 weeks)	A6: GT1 NC GZR+UPR+RZR (8 weeks)
Total subjects affected by serious			

adverse events			
subjects affected / exposed	1 / 14 (7.14%)	0 / 23 (0.00%)	0 / 23 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
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			
Retinal artery occlusion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
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			
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			

subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
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			
Depression			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance-induced psychotic disorder			
subjects affected / exposed	1 / 14 (7.14%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
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			
Device related infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal cyst			

subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
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	A8: GT2 NC GZR+UPR+RZR (8 weeks)	A7: GT2 NC GZR+UPR+EBR (8 weeks)	B6: GT1 NC GZR+UPR+RVR (8 weeks)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
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			
Retinal artery occlusion			

subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
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			
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
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			
Depression			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance-induced psychotic disorder			

subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
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			
Device related infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal cyst			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
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: GT2 NC GZR+UPR+RZR (8 weeks)	B9: GT1 NC GZR+UPR+RZR (12 weeks)	B10: GT2 NC GZR+UPR+RZR (8 weeks) + RBV
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 16 (6.25%)	0 / 48 (0.00%)	2 / 31 (6.45%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma			

subjects affected / exposed	1 / 16 (6.25%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
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			
Retinal artery occlusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
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			
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
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			
Depression			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance-induced psychotic disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
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			
Device related infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal cyst			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			

subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
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: GT2 NC GZR+UPR+RZR (12 weeks)	B12: GT1 C GZR+UPR+RZR (8 weeks)	B13: GT1 C GZR+UPR+RZR (12 weeks)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 31 (0.00%)	1 / 35 (2.86%)	3 / 40 (7.50%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
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			
Retinal artery occlusion			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
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			
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			

subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance-induced psychotic disorder			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Infections and infestations			
Device related infection			

subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pilonidal cyst			
subjects affected / exposed	0 / 31 (0.00%)	1 / 35 (2.86%)	0 / 40 (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
Pneumonia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Serious adverse events	B14: GT2 C GZR+UPR+RZR (12 weeks)	B15: GT2 C GZR+UPR+RZR (12 weeks) + RBV	B16: GT2 C GZR+UPR+RZR+Rasvir (16 weeks)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	2 / 26 (7.69%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			

subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
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			
Retinal artery occlusion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
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			
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
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			
Depression			

subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance-induced psychotic disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
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			
Device related infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal cyst			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	A2: GT1 NC GZR+UPR+RZR (8 weeks)	A1: GT1 NC GZR+UPR+EBR (8 weeks)	A3: GT2 NC GZR+UPR+EBR (8 weeks)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 24 (79.17%)	13 / 23 (56.52%)	10 / 16 (62.50%)
Vascular disorders			
Essential hypertension			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	2 / 24 (8.33%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Hypertension			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Orthostatic hypotension			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 24 (8.33%)	0 / 23 (0.00%)	3 / 16 (18.75%)
occurrences (all)	2	0	3
Chills			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Crying			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Drug withdrawal syndrome			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Energy increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	3 / 24 (12.50%)	4 / 23 (17.39%)	2 / 16 (12.50%)
occurrences (all)	3	5	2
Feeling cold			

subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Influenza like illness subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Oedema peripheral subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	1 / 16 (6.25%) 1
Peripheral swelling subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Vessel puncture site reaction subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Reproductive system and breast disorders Erectile dysfunction subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Menstruation delayed subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Ovarian cyst subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	1 / 16 (6.25%) 1
Dyspnoea subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Dyspnoea exertional			

subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	1 / 24 (4.17%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Flat affect			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Initial insomnia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Irritability			
subjects affected / exposed	1 / 24 (4.17%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0

Libido decreased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Mood altered subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	0 / 23 (0.00%) 0	1 / 16 (6.25%) 1
Sleep disorder subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Investigations			
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	1 / 23 (4.35%) 1	0 / 16 (0.00%) 0
Blood potassium increased subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Electrocardiogram QT prolonged subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	1 / 16 (6.25%) 1
Haemoglobin decreased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	1 / 16 (6.25%) 1
Heart rate decreased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Lipase increased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Liver function test increased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Pulse abnormal			

subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	1 / 16 (6.25%) 1
Weight decreased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Weight increased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	1 / 23 (4.35%) 1	0 / 16 (0.00%) 0
Injury, poisoning and procedural complications			
Accidental overdose subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	0 / 23 (0.00%) 0	1 / 16 (6.25%) 1
Contusion subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Sunburn subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Cardiac disorders			
Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	1 / 23 (4.35%) 1	0 / 16 (0.00%) 0
Sinus bradycardia subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Nervous system disorders			
Disturbance in attention subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	1 / 23 (4.35%) 1	0 / 16 (0.00%) 0
Dysgeusia			

subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	7 / 24 (29.17%)	3 / 23 (13.04%)	3 / 16 (18.75%)
occurrences (all)	9	5	4
Hypoaesthesia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Excessive cerumen production			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Tinnitus			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	1 / 24 (4.17%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Eye disorders			

Blepharospasm subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Vision blurred subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	1 / 23 (4.35%) 1	0 / 16 (0.00%) 0
Gastrointestinal disorders			
Abdominal discomfort subjects affected / exposed occurrences (all)	2 / 24 (8.33%) 2	2 / 23 (8.70%) 2	0 / 16 (0.00%) 0
Abdominal distension subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	2 / 23 (8.70%) 2	2 / 16 (12.50%) 2
Abdominal pain lower subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Constipation subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	1 / 23 (4.35%) 1	1 / 16 (6.25%) 1
Dry mouth subjects affected / exposed occurrences (all)	2 / 24 (8.33%) 2	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Dyspepsia subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Epigastric discomfort			

subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	2 / 24 (8.33%)	1 / 23 (4.35%)	1 / 16 (6.25%)
occurrences (all)	2	2	1
Gastrointestinal disorder			
subjects affected / exposed	0 / 24 (0.00%)	1 / 23 (4.35%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 24 (4.17%)	0 / 23 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
Gingival pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 24 (12.50%)	2 / 23 (8.70%)	1 / 16 (6.25%)
occurrences (all)	3	2	1
Rectal haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 23 (4.35%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Dry skin			
subjects affected / exposed	1 / 24 (4.17%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Erythema			

subjects affected / exposed	0 / 24 (0.00%)	1 / 23 (4.35%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 24 (4.17%)	0 / 23 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
Pruritus generalised			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	2 / 24 (8.33%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	3	0	0
Rash papular			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Renal pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Androgen deficiency			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			

subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 23 (0.00%) 0	0 / 16 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	2 / 24 (8.33%)	2 / 23 (8.70%)	3 / 16 (18.75%)
occurrences (all)	2	2	3
Bursitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 23 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
Cellulitis			

subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	3
Ear infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Gastroenteritis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 23 (4.35%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	1 / 24 (4.17%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 23 (0.00%)	1 / 16 (6.25%)
occurrences (all)	2	0	1
Oral herpes			
subjects affected / exposed	0 / 24 (0.00%)	1 / 23 (4.35%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 23 (4.35%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Sialoadenitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			

subjects affected / exposed	2 / 24 (8.33%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Urinary tract infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 24 (4.17%)	0 / 23 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Increased appetite			
subjects affected / exposed	0 / 24 (0.00%)	0 / 23 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	A4: GT2 NC GZR+UPR+RZR (8 weeks)	A5: GT1 NC GZR+UPR+EBR (8 weeks)	A6: GT1 NC GZR+UPR+RZR (8 weeks)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 14 (71.43%)	15 / 23 (65.22%)	13 / 23 (56.52%)
Vascular disorders			
Essential hypertension			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	1 / 14 (7.14%)	2 / 23 (8.70%)	0 / 23 (0.00%)
occurrences (all)	1	2	0
Hypertension			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 14 (0.00%)	2 / 23 (8.70%)	0 / 23 (0.00%)
occurrences (all)	0	2	0

Chills			
subjects affected / exposed	0 / 14 (0.00%)	1 / 23 (4.35%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Crying			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Drug withdrawal syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Energy increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 14 (14.29%)	6 / 23 (26.09%)	4 / 23 (17.39%)
occurrences (all)	2	6	4
Feeling cold			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 23 (4.35%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Vessel puncture site reaction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

Erectile dysfunction subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 23 (0.00%) 0	0 / 23 (0.00%) 0
Menstruation delayed subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 23 (0.00%) 0	0 / 23 (0.00%) 0
Ovarian cyst subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 23 (0.00%) 0	0 / 23 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	1 / 23 (4.35%) 1	1 / 23 (4.35%) 1
Dyspnoea subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	1 / 23 (4.35%) 1	0 / 23 (0.00%) 0
Dyspnoea exertional subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 23 (0.00%) 0	0 / 23 (0.00%) 0
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	1 / 23 (4.35%) 1	0 / 23 (0.00%) 0
Respiratory tract congestion subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 23 (0.00%) 0	0 / 23 (0.00%) 0
Rhinorrhoea subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	1 / 23 (4.35%) 1	0 / 23 (0.00%) 0
Throat irritation subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	0 / 23 (0.00%) 0	0 / 23 (0.00%) 0
Psychiatric disorders			
Affective disorder subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 23 (0.00%) 0	0 / 23 (0.00%) 0
Anxiety			

subjects affected / exposed	1 / 14 (7.14%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Flat affect			
subjects affected / exposed	1 / 14 (7.14%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Initial insomnia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	2 / 14 (14.29%)	1 / 23 (4.35%)	0 / 23 (0.00%)
occurrences (all)	2	1	0
Irritability			
subjects affected / exposed	1 / 14 (7.14%)	1 / 23 (4.35%)	0 / 23 (0.00%)
occurrences (all)	1	1	0
Libido decreased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Mood altered			
subjects affected / exposed	0 / 14 (0.00%)	1 / 23 (4.35%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Sleep disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			

subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Heart rate decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Pulse abnormal			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Contusion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Sunburn			

subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 23 (0.00%) 0	0 / 23 (0.00%) 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 14 (0.00%)	2 / 23 (8.70%)	0 / 23 (0.00%)
occurrences (all)	0	3	0
Sinus bradycardia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 14 (0.00%)	4 / 23 (17.39%)	0 / 23 (0.00%)
occurrences (all)	0	5	0
Dysgeusia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	2
Headache			
subjects affected / exposed	2 / 14 (14.29%)	8 / 23 (34.78%)	3 / 23 (13.04%)
occurrences (all)	2	9	4
Hypoaesthesia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	2 / 14 (14.29%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
Paraesthesia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Syncope			

subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	1 / 23 (4.35%) 1	0 / 23 (0.00%) 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Excessive cerumen production			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Eye disorders			
Blepharospasm			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 14 (7.14%)	1 / 23 (4.35%)	1 / 23 (4.35%)
occurrences (all)	1	1	1
Abdominal distension			
subjects affected / exposed	0 / 14 (0.00%)	1 / 23 (4.35%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	2
Abdominal pain lower			

subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Abdominal pain upper			
subjects affected / exposed	1 / 14 (7.14%)	0 / 23 (0.00%)	1 / 23 (4.35%)
occurrences (all)	1	0	1
Constipation			
subjects affected / exposed	0 / 14 (0.00%)	1 / 23 (4.35%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	0 / 14 (0.00%)	4 / 23 (17.39%)	1 / 23 (4.35%)
occurrences (all)	0	4	1
Dry mouth			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Epigastric discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 14 (0.00%)	2 / 23 (8.70%)	1 / 23 (4.35%)
occurrences (all)	0	3	1
Gastrointestinal disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 14 (7.14%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Gingival pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 14 (14.29%)	3 / 23 (13.04%)	0 / 23 (0.00%)
occurrences (all)	3	3	0
Rectal haemorrhage			

subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	2
Pruritus generalised			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 14 (7.14%)	1 / 23 (4.35%)	0 / 23 (0.00%)
occurrences (all)	1	2	0
Rash papular			

subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 23 (0.00%) 0	0 / 23 (0.00%) 0
Vitiligo subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 23 (0.00%) 0	0 / 23 (0.00%) 0
Renal and urinary disorders Pollakiuria subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	0 / 23 (0.00%) 0	0 / 23 (0.00%) 0
Renal pain subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	0 / 23 (0.00%) 0	0 / 23 (0.00%) 0
Endocrine disorders Androgen deficiency subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 23 (0.00%) 0	0 / 23 (0.00%) 0
Hypothyroidism subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 23 (0.00%) 0	0 / 23 (0.00%) 0
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	3 / 23 (13.04%) 4	1 / 23 (4.35%) 1
Back pain subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	1 / 23 (4.35%) 1	0 / 23 (0.00%) 0
Bursitis subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	0 / 23 (0.00%) 0	0 / 23 (0.00%) 0
Muscle spasms subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 23 (0.00%) 0	0 / 23 (0.00%) 0
Muscular weakness subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 23 (0.00%) 0	0 / 23 (0.00%) 0
Musculoskeletal pain			

subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	1 / 14 (7.14%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0

Oral herpes			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Sialoadenitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	1 / 14 (7.14%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 14 (7.14%)	0 / 23 (0.00%)	1 / 23 (4.35%)
occurrences (all)	1	0	1
Urinary tract infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Increased appetite			
subjects affected / exposed	0 / 14 (0.00%)	0 / 23 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Non-serious adverse events	A8: GT2 NC GZR+UPR+RZR (8 weeks)	A7: GT2 NC GZR+UPR+EBR (8 weeks)	B6: GT1 NC GZR+UPR+RVR (8 weeks)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 16 (75.00%)	13 / 15 (86.67%)	18 / 30 (60.00%)

Vascular disorders			
Essential hypertension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Hot flush			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 16 (6.25%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	1	1	0
Chills			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Crying			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Drug withdrawal syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Energy increased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	6 / 16 (37.50%)	6 / 15 (40.00%)	4 / 30 (13.33%)
occurrences (all)	6	6	4
Feeling cold			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			

subjects affected / exposed	0 / 16 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Vessel puncture site reaction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Menstruation delayed			
subjects affected / exposed	1 / 16 (6.25%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Ovarian cyst			
subjects affected / exposed	0 / 16 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 16 (0.00%)	1 / 15 (6.67%)	1 / 30 (3.33%)
occurrences (all)	0	1	1
Dyspnoea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 16 (0.00%)	2 / 15 (13.33%)	1 / 30 (3.33%)
occurrences (all)	0	3	1
Oropharyngeal pain			

subjects affected / exposed occurrences (all)	2 / 16 (12.50%) 2	1 / 15 (6.67%) 1	0 / 30 (0.00%) 0
Respiratory tract congestion subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Rhinorrhoea subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	1 / 15 (6.67%) 1	0 / 30 (0.00%) 0
Throat irritation subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Psychiatric disorders			
Affective disorder subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Anxiety subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Depression subjects affected / exposed occurrences (all)	2 / 16 (12.50%) 2	2 / 15 (13.33%) 3	0 / 30 (0.00%) 0
Flat affect subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Initial insomnia subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Insomnia subjects affected / exposed occurrences (all)	2 / 16 (12.50%) 2	2 / 15 (13.33%) 3	3 / 30 (10.00%) 3
Irritability subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Libido decreased subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	1 / 30 (3.33%) 1

Mood altered subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Sleep disorder subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	1 / 30 (3.33%) 1
Investigations			
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 3	0 / 15 (0.00%) 0	1 / 30 (3.33%) 1
Blood potassium increased subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 15 (6.67%) 1	0 / 30 (0.00%) 0
Electrocardiogram QT prolonged subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	1 / 30 (3.33%) 1
Haemoglobin decreased subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	2 / 15 (13.33%) 2	0 / 30 (0.00%) 0
Heart rate decreased subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Lipase increased subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 15 (6.67%) 1	0 / 30 (0.00%) 0
Liver function test increased subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Pulse abnormal subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Weight decreased			

subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Weight increased subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Injury, poisoning and procedural complications			
Accidental overdose subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	1 / 15 (6.67%) 1	1 / 30 (3.33%) 1
Contusion subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 15 (6.67%) 1	0 / 30 (0.00%) 0
Sunburn subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Cardiac disorders			
Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	1 / 15 (6.67%) 1	0 / 30 (0.00%) 0
Sinus bradycardia subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Nervous system disorders			
Disturbance in attention subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	4 / 15 (26.67%) 5	1 / 30 (3.33%) 1
Dysgeusia subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 15 (0.00%) 0	1 / 30 (3.33%) 1
Headache			

subjects affected / exposed	9 / 16 (56.25%)	5 / 15 (33.33%)	2 / 30 (6.67%)
occurrences (all)	10	5	2
Hypoaesthesia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Lethargy			
subjects affected / exposed	1 / 16 (6.25%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	1	1	0
Paraesthesia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Syncope			
subjects affected / exposed	1 / 16 (6.25%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	3 / 30 (10.00%)
occurrences (all)	0	0	4
Ear and labyrinth disorders			
Excessive cerumen production			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	1 / 16 (6.25%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Vertigo			
subjects affected / exposed	0 / 16 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Blepharospasm			
subjects affected / exposed	1 / 16 (6.25%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Vision blurred			

subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 16 (6.25%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	1	1	0
Abdominal distension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 16 (6.25%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	1	1	0
Abdominal pain lower			
subjects affected / exposed	0 / 16 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	2	0
Abdominal pain upper			
subjects affected / exposed	1 / 16 (6.25%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	0 / 16 (0.00%)	2 / 15 (13.33%)	2 / 30 (6.67%)
occurrences (all)	0	2	2
Diarrhoea			
subjects affected / exposed	2 / 16 (12.50%)	0 / 15 (0.00%)	3 / 30 (10.00%)
occurrences (all)	2	0	3
Dry mouth			
subjects affected / exposed	1 / 16 (6.25%)	0 / 15 (0.00%)	3 / 30 (10.00%)
occurrences (all)	1	0	3
Dyspepsia			
subjects affected / exposed	0 / 16 (0.00%)	3 / 15 (20.00%)	0 / 30 (0.00%)
occurrences (all)	0	3	0
Epigastric discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	2 / 16 (12.50%)	3 / 15 (20.00%)	0 / 30 (0.00%)
occurrences (all)	2	3	0

Gastrointestinal disorder subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Gingival pain subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	3 / 16 (18.75%) 3	6 / 15 (40.00%) 8	5 / 30 (16.67%) 5
Rectal haemorrhage subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	2 / 30 (6.67%) 2
Hepatobiliary disorders Hepatic pain subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 15 (6.67%) 1	0 / 30 (0.00%) 0
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Dry skin subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	2 / 15 (13.33%) 2	0 / 30 (0.00%) 0
Erythema subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Hyperhidrosis subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Macule			

subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Pruritus			
subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	3 / 15 (20.00%) 3	0 / 30 (0.00%) 0
Pruritus generalised			
subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	1 / 30 (3.33%) 3
Rash			
subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	1 / 15 (6.67%) 1	0 / 30 (0.00%) 0
Rash papular			
subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Vitiligo			
subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 15 (6.67%) 1	0 / 30 (0.00%) 0
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Renal pain			
subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Endocrine disorders			
Androgen deficiency			
subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 15 (6.67%) 1	0 / 30 (0.00%) 0
Hypothyroidism			
subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 15 (0.00%) 0	0 / 30 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 15 (0.00%) 0	2 / 30 (6.67%) 3
Back pain			

subjects affected / exposed	2 / 16 (12.50%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	2	0	1
Bursitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 16 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Muscular weakness			
subjects affected / exposed	1 / 16 (6.25%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 16 (0.00%)	3 / 15 (20.00%)	0 / 30 (0.00%)
occurrences (all)	0	3	0
Pain in extremity			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0

Gastroenteritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 15 (6.67%)	1 / 30 (3.33%)
occurrences (all)	0	1	1
Influenza			
subjects affected / exposed	0 / 16 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	3 / 16 (18.75%)	3 / 15 (20.00%)	0 / 30 (0.00%)
occurrences (all)	3	4	0
Oral herpes			
subjects affected / exposed	0 / 16 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Sialoadenitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Tooth abscess			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	2
Upper respiratory tract infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	2 / 30 (6.67%)
occurrences (all)	0	0	3
Urinary tract infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	0 / 16 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Increased appetite			
subjects affected / exposed	2 / 16 (12.50%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0

Non-serious adverse events	B8: GT2 NC GZR+UPR+RZR (8 weeks)	B9: GT1 NC GZR+UPR+RZR (12 weeks)	B10: GT2 NC GZR+UPR+RZR (8 weeks) + RBV
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 16 (68.75%)	35 / 48 (72.92%)	24 / 31 (77.42%)
Vascular disorders			
Essential hypertension			
subjects affected / exposed	1 / 16 (6.25%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Hot flush			
subjects affected / exposed	0 / 16 (0.00%)	2 / 48 (4.17%)	0 / 31 (0.00%)
occurrences (all)	0	2	0
Hypertension			
subjects affected / exposed	0 / 16 (0.00%)	2 / 48 (4.17%)	0 / 31 (0.00%)
occurrences (all)	0	2	0
Orthostatic hypotension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 16 (12.50%)	0 / 48 (0.00%)	3 / 31 (9.68%)
occurrences (all)	2	0	3
Chills			
subjects affected / exposed	0 / 16 (0.00%)	1 / 48 (2.08%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Crying			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Drug withdrawal syndrome			

subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Energy increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	3 / 16 (18.75%)	8 / 48 (16.67%)	4 / 31 (12.90%)
occurrences (all)	4	9	4
Feeling cold			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 16 (6.25%)	1 / 48 (2.08%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Oedema peripheral			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site reaction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Menstruation delayed			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Ovarian cyst			

subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 48 (0.00%) 0	0 / 31 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 16 (0.00%)	3 / 48 (6.25%)	4 / 31 (12.90%)
occurrences (all)	0	3	5
Dyspnoea			
subjects affected / exposed	1 / 16 (6.25%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 16 (0.00%)	2 / 48 (4.17%)	1 / 31 (3.23%)
occurrences (all)	0	2	1
Respiratory tract congestion			
subjects affected / exposed	0 / 16 (0.00%)	1 / 48 (2.08%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 16 (0.00%)	1 / 48 (2.08%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 16 (0.00%)	2 / 48 (4.17%)	1 / 31 (3.23%)
occurrences (all)	0	2	1
Depression			
subjects affected / exposed	0 / 16 (0.00%)	2 / 48 (4.17%)	2 / 31 (6.45%)
occurrences (all)	0	2	3
Flat affect			

subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Initial insomnia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 16 (6.25%)	4 / 48 (8.33%)	4 / 31 (12.90%)
occurrences (all)	1	5	4
Irritability			
subjects affected / exposed	2 / 16 (12.50%)	1 / 48 (2.08%)	2 / 31 (6.45%)
occurrences (all)	2	1	2
Libido decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Mood altered			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 48 (2.08%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 48 (0.00%)	1 / 31 (3.23%)
occurrences (all)	1	0	1
Blood potassium increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			

subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Heart rate decreased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Lipase increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Pulse abnormal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 48 (2.08%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 16 (0.00%)	2 / 48 (4.17%)	2 / 31 (6.45%)
occurrences (all)	0	2	2
Contusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Palpitations			

subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 48 (0.00%) 0	1 / 31 (3.23%) 1
Sinus bradycardia subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 48 (0.00%) 0	0 / 31 (0.00%) 0
Nervous system disorders			
Disturbance in attention subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 48 (0.00%) 0	1 / 31 (3.23%) 1
Dizziness subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 48 (2.08%) 4	0 / 31 (0.00%) 0
Dysgeusia subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 48 (2.08%) 1	2 / 31 (6.45%) 2
Headache subjects affected / exposed occurrences (all)	3 / 16 (18.75%) 3	15 / 48 (31.25%) 25	8 / 31 (25.81%) 8
Hypoaesthesia subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 48 (2.08%) 1	0 / 31 (0.00%) 0
Lethargy subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 48 (0.00%) 0	1 / 31 (3.23%) 2
Paraesthesia subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 48 (2.08%) 1	1 / 31 (3.23%) 1
Syncope subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 48 (0.00%) 0	0 / 31 (0.00%) 0
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 48 (0.00%) 0	0 / 31 (0.00%) 0
Lymphadenopathy			

subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 48 (2.08%) 1	0 / 31 (0.00%) 0
Ear and labyrinth disorders			
Excessive cerumen production subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 48 (0.00%) 0	0 / 31 (0.00%) 0
Tinnitus subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 48 (0.00%) 0	1 / 31 (3.23%) 1
Vertigo subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 48 (2.08%) 1	0 / 31 (0.00%) 0
Eye disorders			
Blepharospasm subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 48 (0.00%) 0	0 / 31 (0.00%) 0
Vision blurred subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 48 (0.00%) 0	0 / 31 (0.00%) 0
Gastrointestinal disorders			
Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 48 (0.00%) 0	0 / 31 (0.00%) 0
Abdominal distension subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	1 / 48 (2.08%) 1	0 / 31 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 48 (2.08%) 1	1 / 31 (3.23%) 1
Abdominal pain lower subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 48 (0.00%) 0	0 / 31 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 48 (0.00%) 0	1 / 31 (3.23%) 1
Constipation			

subjects affected / exposed	2 / 16 (12.50%)	1 / 48 (2.08%)	2 / 31 (6.45%)
occurrences (all)	2	1	2
Diarrhoea			
subjects affected / exposed	1 / 16 (6.25%)	5 / 48 (10.42%)	4 / 31 (12.90%)
occurrences (all)	1	5	4
Dry mouth			
subjects affected / exposed	0 / 16 (0.00%)	2 / 48 (4.17%)	1 / 31 (3.23%)
occurrences (all)	0	2	1
Dyspepsia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	2	0	0
Epigastric discomfort			
subjects affected / exposed	1 / 16 (6.25%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Flatulence			
subjects affected / exposed	0 / 16 (0.00%)	3 / 48 (6.25%)	0 / 31 (0.00%)
occurrences (all)	0	3	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 16 (0.00%)	2 / 48 (4.17%)	0 / 31 (0.00%)
occurrences (all)	0	2	0
Gingival pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	2 / 16 (12.50%)	7 / 48 (14.58%)	5 / 31 (16.13%)
occurrences (all)	3	7	6
Rectal haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 16 (0.00%)	2 / 48 (4.17%)	1 / 31 (3.23%)
occurrences (all)	0	2	1
Hepatobiliary disorders			

Hepatic pain subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 48 (0.00%) 0	0 / 31 (0.00%) 0
Skin and subcutaneous tissue disorders			
Alopecia subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 48 (0.00%) 0	0 / 31 (0.00%) 0
Dry skin subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 48 (0.00%) 0	3 / 31 (9.68%) 3
Erythema subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 48 (0.00%) 0	1 / 31 (3.23%) 1
Hyperhidrosis subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	2 / 48 (4.17%) 2	0 / 31 (0.00%) 0
Macule subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 48 (0.00%) 0	0 / 31 (0.00%) 0
Pruritus subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 48 (2.08%) 1	5 / 31 (16.13%) 5
Pruritus generalised subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 48 (0.00%) 0	0 / 31 (0.00%) 0
Rash subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 48 (2.08%) 1	3 / 31 (9.68%) 5
Rash papular subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 48 (0.00%) 0	0 / 31 (0.00%) 0
Vitiligo subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 48 (0.00%) 0	0 / 31 (0.00%) 0
Renal and urinary disorders			

Pollakiuria			
subjects affected / exposed	0 / 16 (0.00%)	1 / 48 (2.08%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Renal pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Androgen deficiency			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 16 (18.75%)	1 / 48 (2.08%)	3 / 31 (9.68%)
occurrences (all)	3	2	3
Back pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 48 (2.08%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Bursitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	1 / 16 (6.25%)	0 / 48 (0.00%)	1 / 31 (3.23%)
occurrences (all)	1	0	3
Muscular weakness			
subjects affected / exposed	0 / 16 (0.00%)	1 / 48 (2.08%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal pain			
subjects affected / exposed	2 / 16 (12.50%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Myalgia			

subjects affected / exposed	0 / 16 (0.00%)	2 / 48 (4.17%)	1 / 31 (3.23%)
occurrences (all)	0	3	1
Pain in extremity			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Cellulitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	2 / 31 (6.45%)
occurrences (all)	0	0	2
Gingivitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 16 (0.00%)	3 / 48 (6.25%)	0 / 31 (0.00%)
occurrences (all)	0	3	0
Nasopharyngitis			
subjects affected / exposed	1 / 16 (6.25%)	1 / 48 (2.08%)	3 / 31 (9.68%)
occurrences (all)	1	1	3
Oral herpes			
subjects affected / exposed	0 / 16 (0.00%)	1 / 48 (2.08%)	0 / 31 (0.00%)
occurrences (all)	0	2	0
Pneumonia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0

Sialoadenitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 16 (12.50%)	1 / 48 (2.08%)	1 / 31 (3.23%)
occurrences (all)	2	1	1
Urinary tract infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 16 (0.00%)	1 / 48 (2.08%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Increased appetite			
subjects affected / exposed	0 / 16 (0.00%)	0 / 48 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1

Non-serious adverse events	B11: GT2 NC GZR+UPR+RZR (12 weeks)	B12: GT1 C GZR+UPR+RZR (8 weeks)	B13: GT1 C GZR+UPR+RZR (12 weeks)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 31 (61.29%)	19 / 35 (54.29%)	26 / 40 (65.00%)
Vascular disorders			
Essential hypertension			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	1 / 31 (3.23%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0

Hypertension			
subjects affected / exposed	1 / 31 (3.23%)	3 / 35 (8.57%)	2 / 40 (5.00%)
occurrences (all)	1	3	2
Orthostatic hypotension			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 31 (3.23%)	1 / 35 (2.86%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
Chills			
subjects affected / exposed	2 / 31 (6.45%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
Crying			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Drug withdrawal syndrome			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Energy increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 31 (3.23%)	3 / 35 (8.57%)	3 / 40 (7.50%)
occurrences (all)	1	3	3
Feeling cold			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	2
Oedema peripheral			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			

subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Vessel puncture site reaction subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Reproductive system and breast disorders Erectile dysfunction subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Menstruation delayed subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Ovarian cyst subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Dyspnoea subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Dyspnoea exertional subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Oropharyngeal pain subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1	0 / 35 (0.00%) 0	2 / 40 (5.00%) 2
Respiratory tract congestion subjects affected / exposed occurrences (all)	2 / 31 (6.45%) 2	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Rhinorrhoea			

subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	2 / 31 (6.45%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
Depression			
subjects affected / exposed	2 / 31 (6.45%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
Flat affect			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Initial insomnia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	2 / 31 (6.45%)	0 / 35 (0.00%)	3 / 40 (7.50%)
occurrences (all)	2	0	3
Irritability			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Libido decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Mood altered			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Blood potassium increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Heart rate decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	1 / 31 (3.23%)	0 / 35 (0.00%)	1 / 40 (2.50%)
occurrences (all)	1	0	1
Liver function test increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Pulse abnormal			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Accidental overdose subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	1 / 35 (2.86%) 1	0 / 40 (0.00%) 0
Contusion subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Sunburn subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Cardiac disorders			
Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 2	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Sinus bradycardia subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Nervous system disorders			
Disturbance in attention subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	1 / 35 (2.86%) 1	1 / 40 (2.50%) 1
Dysgeusia subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	7 / 31 (22.58%) 7	5 / 35 (14.29%) 6	5 / 40 (12.50%) 11
Hypoaesthesia subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Lethargy			

subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	1 / 40 (2.50%) 1
Paraesthesia subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	1 / 35 (2.86%) 1	0 / 40 (0.00%) 0
Syncope subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	1 / 35 (2.86%) 1	0 / 40 (0.00%) 0
Ear and labyrinth disorders Excessive cerumen production subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Tinnitus subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	2 / 40 (5.00%) 3
Eye disorders Blepharospasm subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Vision blurred subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Gastrointestinal disorders Abdominal discomfort subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1	1 / 35 (2.86%) 1	0 / 40 (0.00%) 0
Abdominal distension			

subjects affected / exposed	1 / 31 (3.23%)	0 / 35 (0.00%)	1 / 40 (2.50%)
occurrences (all)	1	0	1
Abdominal pain			
subjects affected / exposed	0 / 31 (0.00%)	1 / 35 (2.86%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
Abdominal pain lower			
subjects affected / exposed	0 / 31 (0.00%)	1 / 35 (2.86%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	1 / 31 (3.23%)	2 / 35 (5.71%)	0 / 40 (0.00%)
occurrences (all)	1	2	0
Constipation			
subjects affected / exposed	0 / 31 (0.00%)	1 / 35 (2.86%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	1 / 31 (3.23%)	1 / 35 (2.86%)	1 / 40 (2.50%)
occurrences (all)	1	1	1
Dry mouth			
subjects affected / exposed	1 / 31 (3.23%)	0 / 35 (0.00%)	1 / 40 (2.50%)
occurrences (all)	1	0	1
Dyspepsia			
subjects affected / exposed	1 / 31 (3.23%)	0 / 35 (0.00%)	1 / 40 (2.50%)
occurrences (all)	1	0	1
Epigastric discomfort			
subjects affected / exposed	0 / 31 (0.00%)	1 / 35 (2.86%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	2 / 31 (6.45%)	1 / 35 (2.86%)	1 / 40 (2.50%)
occurrences (all)	2	1	1
Gastrointestinal disorder			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	2
Gingival pain			

subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1	1 / 35 (2.86%) 1	3 / 40 (7.50%) 3
Rectal haemorrhage subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	1 / 40 (2.50%) 1
Hepatobiliary disorders Hepatic pain subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Dry skin subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	1 / 40 (2.50%) 1
Erythema subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Hyperhidrosis subjects affected / exposed occurrences (all)	2 / 31 (6.45%) 2	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Macule subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Pruritus subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1	0 / 35 (0.00%) 0	1 / 40 (2.50%) 1
Pruritus generalised			

subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Rash subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	1 / 40 (2.50%) 1
Rash papular subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Vitiligo subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Renal and urinary disorders Pollakiuria subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Renal pain subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Endocrine disorders Androgen deficiency subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Hypothyroidism subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1	1 / 35 (2.86%) 1	3 / 40 (7.50%) 3
Back pain subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1	0 / 35 (0.00%) 0	1 / 40 (2.50%) 1
Bursitis subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 35 (0.00%) 0	0 / 40 (0.00%) 0
Muscle spasms			

subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	3
Muscular weakness			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Musculoskeletal stiffness			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	2 / 31 (6.45%)	1 / 35 (2.86%)	2 / 40 (5.00%)
occurrences (all)	3	1	2
Pain in extremity			
subjects affected / exposed	0 / 31 (0.00%)	1 / 35 (2.86%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	2
Cystitis			
subjects affected / exposed	0 / 31 (0.00%)	2 / 35 (5.71%)	0 / 40 (0.00%)
occurrences (all)	0	3	0
Ear infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Gingivitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

Influenza			
subjects affected / exposed	1 / 31 (3.23%)	0 / 35 (0.00%)	1 / 40 (2.50%)
occurrences (all)	1	0	1
Nasopharyngitis			
subjects affected / exposed	1 / 31 (3.23%)	1 / 35 (2.86%)	3 / 40 (7.50%)
occurrences (all)	1	1	4
Oral herpes			
subjects affected / exposed	0 / 31 (0.00%)	1 / 35 (2.86%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Sialoadenitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 31 (3.23%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Tooth abscess			
subjects affected / exposed	1 / 31 (3.23%)	0 / 35 (0.00%)	1 / 40 (2.50%)
occurrences (all)	1	0	1
Upper respiratory tract infection			
subjects affected / exposed	3 / 31 (9.68%)	0 / 35 (0.00%)	1 / 40 (2.50%)
occurrences (all)	3	0	1
Urinary tract infection			
subjects affected / exposed	1 / 31 (3.23%)	1 / 35 (2.86%)	1 / 40 (2.50%)
occurrences (all)	1	1	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Increased appetite			

subjects affected / exposed	0 / 31 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	B14: GT2 C GZR+UPR+RZR (12 weeks)	B15: GT2 C GZR+UPR+RZR (12 weeks) + RBV	B16: GT2 C GZR+UPR+RZRasvir (16 weeks)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 15 (53.33%)	13 / 16 (81.25%)	14 / 26 (53.85%)
Vascular disorders			
Essential hypertension			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Orthostatic hypotension			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 15 (0.00%)	3 / 16 (18.75%)	1 / 26 (3.85%)
occurrences (all)	0	5	2
Chills			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Crying			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Drug withdrawal syndrome			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Energy increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Fatigue			

subjects affected / exposed	1 / 15 (6.67%)	5 / 16 (31.25%)	3 / 26 (11.54%)
occurrences (all)	1	5	4
Feeling cold			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Peripheral swelling			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site reaction			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 26 (0.00%)
occurrences (all)	0	3	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Menstruation delayed			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Ovarian cyst			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	2 / 26 (7.69%)
occurrences (all)	0	0	2
Dyspnoea			

subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	1 / 26 (3.85%)
occurrences (all)	0	1	1
Dyspnoea exertional			
subjects affected / exposed	1 / 15 (6.67%)	1 / 16 (6.25%)	1 / 26 (3.85%)
occurrences (all)	1	1	1
Oropharyngeal pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Throat irritation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Anxiety			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Depression			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	1 / 26 (3.85%)
occurrences (all)	0	1	1
Flat affect			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Initial insomnia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 15 (0.00%)	2 / 16 (12.50%)	1 / 26 (3.85%)
occurrences (all)	0	2	1

Irritability			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Libido decreased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Mood altered			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 26 (0.00%)
occurrences (all)	0	2	0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 15 (0.00%)	2 / 16 (12.50%)	0 / 26 (0.00%)
occurrences (all)	0	2	0
Heart rate decreased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Liver function test increased			

subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 16 (0.00%) 0	0 / 26 (0.00%) 0
Pulse abnormal subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 26 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 16 (6.25%) 1	1 / 26 (3.85%) 1
Weight increased subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 16 (0.00%) 0	0 / 26 (0.00%) 0
Injury, poisoning and procedural complications Accidental overdose subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	1 / 16 (6.25%) 1	0 / 26 (0.00%) 0
Contusion subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 26 (0.00%) 0
Sunburn subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 16 (6.25%) 1	0 / 26 (0.00%) 0
Cardiac disorders Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	2 / 26 (7.69%) 2
Palpitations subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	2 / 16 (12.50%) 3	0 / 26 (0.00%) 0
Sinus bradycardia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 26 (0.00%) 0
Nervous system disorders Disturbance in attention subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 16 (0.00%) 0	0 / 26 (0.00%) 0
Dizziness			

subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Dysgeusia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 15 (13.33%)	2 / 16 (12.50%)	4 / 26 (15.38%)
occurrences (all)	2	2	10
Hypoaesthesia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Lethargy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 15 (6.67%)	1 / 16 (6.25%)	0 / 26 (0.00%)
occurrences (all)	1	2	0
Lymphadenopathy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Excessive cerumen production			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Vertigo			

subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 26 (0.00%) 0
Eye disorders			
Blepharospasm			
subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 26 (0.00%) 0
Vision blurred			
subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 26 (0.00%) 0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 16 (6.25%) 1	1 / 26 (3.85%) 1
Abdominal distension			
subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	1 / 26 (3.85%) 1
Abdominal pain			
subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	3 / 26 (11.54%) 3
Abdominal pain lower			
subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 26 (0.00%) 0
Abdominal pain upper			
subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	1 / 16 (6.25%) 1	4 / 26 (15.38%) 4
Constipation			
subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	1 / 26 (3.85%) 1
Diarrhoea			
subjects affected / exposed occurrences (all)	2 / 15 (13.33%) 2	1 / 16 (6.25%) 1	1 / 26 (3.85%) 1
Dry mouth			
subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	2 / 26 (7.69%) 2
Dyspepsia			

subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Epigastric discomfort			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	2 / 26 (7.69%)
occurrences (all)	0	0	3
Gastrointestinal disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 15 (13.33%)	3 / 16 (18.75%)	4 / 26 (15.38%)
occurrences (all)	2	3	4
Rectal haemorrhage			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 15 (0.00%)	3 / 16 (18.75%)	2 / 26 (7.69%)
occurrences (all)	0	3	3
Hepatobiliary disorders			
Hepatic pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Dry skin			

subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Pruritus generalised			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	1 / 26 (3.85%)
occurrences (all)	2	0	1
Rash papular			
subjects affected / exposed	1 / 15 (6.67%)	2 / 16 (12.50%)	0 / 26 (0.00%)
occurrences (all)	1	2	0
Vitiligo			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Renal pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Androgen deficiency			

subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	2 / 26 (7.69%)
occurrences (all)	0	0	2
Back pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Muscular weakness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	1 / 26 (3.85%)
occurrences (all)	1	0	2
Infections and infestations			

Bronchitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Cystitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Gingivitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	2
Oral herpes			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Sialoadenitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0

Tooth abscess subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 26 (0.00%) 0
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 16 (6.25%) 2	0 / 26 (0.00%) 0
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 16 (6.25%) 1	1 / 26 (3.85%) 1
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	0 / 26 (0.00%) 0
Diabetes mellitus inadequate control subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 16 (6.25%) 1	0 / 26 (0.00%) 0
Increased appetite subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 16 (0.00%) 0	1 / 26 (3.85%) 1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 December 2014	Amendment 01: The primary purpose of this amendment was to add additional doses and to increase treatment duration.
12 June 2015	Amendment 03: The primary purpose of this amendment was to add additional arms in a step-wise approach to limit the number of participants exposed to potentially suboptimal treatment regimens.
02 November 2015	Amendment 05: The primary purpose of this amendment was to update Part B based on interim results from Part A, and to also add cirrhotic participants.
09 June 2016	Amendment 07: The primary purpose of this amendment was to include enrolled participants with virologic failure on study to a follow-up study (MK-5172-017).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported