



Clinical trial results:

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

Summary

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

Results information

| | |
|--------------------------------|----------------|
| Result version number | v2 (current) |
| This version publication date | 05 August 2018 |
| First version publication date | 13 May 2018 |
| Version creation reason | |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | 3682-012 |
|-----------------------|----------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Merck Sharp & Dohme Corp. |
| Sponsor organisation address | 2000 Galloping Hill Road, Kenilworth, NJ, United States, 07033 |
| Public contact | Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com |
| Scientific contact | Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com |

Notes:

Paediatric regulatory details

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|--|----|
| 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

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|--|-------------|
| Analysis stage | Final |
| Date of interim/final analysis | 03 May 2017 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 03 May 2017 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

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

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

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

Notes:

Population of trial subjects

Subjects enrolled per country

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

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

Notes:

| Subjects enrolled per age group | |
|---|-----|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 394 |
| From 65 to 84 years | 19 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

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

Pre-assignment

Screening details:

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

Period 1

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

Arms

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

Arm description:

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

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

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

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

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

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

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

Arm description:

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

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

Dosage and administration details:

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

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

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

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

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

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

Dosage and administration details:

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

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

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

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

Dosage and administration details:

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

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

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

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

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

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

Dosage and administration details:

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

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

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

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

Dosage and administration details:

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

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

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

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

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

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

Dosage and administration details:

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

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

Arm description:

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

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

Dosage and administration details:

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

q.d. by mouth.

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

Dosage and administration details:

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

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

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

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

Dosage and administration details:

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

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

Arm description:

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

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

Dosage and administration details:

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

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

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

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

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

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

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

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

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

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

Period 2

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

Arms

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

Arm description:

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

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

Arm description:

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

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

Arm description:

Part A: HCV GT3-infected NC TN participants received grazoprevir (100 mg) + uprifosbuvir (450 mg) + elbasvir (50 mg) q.d. by mouth for 8 weeks.

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

Arm description:

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

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

Arm description:

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

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

Dosage and administration details:

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

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

Arm description:

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

by mouth for 8 weeks.

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

Arm description:

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

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

Dosage and administration details:

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

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

Arm description:

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

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

Arm description:

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

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

Dosage and administration details:

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

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

Arm description:

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

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

Dosage and administration details:

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

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

Arm description:

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

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

Arm description:

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

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

Dosage and administration details:

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

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

Arm description:

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

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

Dosage and administration details:

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

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

Arm description:

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

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

Dosage and administration details:

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

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

| | |
|--|---|
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| Part B: RBV 200 mg capsules taken b.i.d. by mouth at a total daily dose of 800 mg - 1400 mg based on participant body weight. | |
| Arm title | B18: GT3 C TE MK-3682B (16 weeks) |
| Arm description: | |
| Part B: HCV GT3-infected C TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 16 weeks. | |
| Arm type | Experimental |
| Investigational medicinal product name | MK-3682B |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth. | |
| Arm title | B19: GT3 C TE MK-3682B + RBV (16 weeks) |
| Arm description: | |
| Part B: HCV GT3-infected C TE participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d., and RBV (weight-based dosing) b.i.d., by mouth for 16 weeks. | |
| Arm type | Experimental |
| Investigational medicinal product name | Ribavirin |
| Investigational medicinal product code | |
| Other name | Rebetol |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| Part B: RBV 200 mg capsules taken b.i.d. by mouth at a total daily dose of 800 mg - 1400 mg based on participant body weight. | |
| Investigational medicinal product name | MK-3682B |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth. | |
| Arm title | B20: GT4 NC TN MK-3682B (8 weeks) |
| Arm description: | |
| Part B: HCV GT4-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 8 weeks. | |
| Arm type | Experimental |
| Investigational medicinal product name | MK-3682B |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| Part B: two FDC tablets, each containing grazoprevir 50 mg + elbasvir 225 mg + ruzasvir 30 mg, taken q.d. by mouth. | |

| | |
|--|------------------------------------|
| Arm title | B22: GT6 NC TN MK-3682B (12 weeks) |
| Arm description: Part B: HCV GT6-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 12 weeks. | |
| Arm type | Experimental |
| Investigational medicinal product name | MK-3682B |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

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

Notes:

[1] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period.

Justification: Baseline participants include participants who received at least one dose of study drug. One 'B18: GT3 C TE MK-3682B (16 weeks)' participant did not receive any study drug.

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

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

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

| | | | |
|-------------------|---|---|---|
| Lost to follow-up | 1 | 1 | - |
|-------------------|---|---|---|

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

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

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

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

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

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

Notes:

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

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

Period 3

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

Arms

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

Arm description:

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

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

Arm description:

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

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

Arm description:

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

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

Arm description:

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

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

Dosage and administration details:

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

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

Dosage and administration details:

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

q.d. by mouth.

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

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

Notes:

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

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

Baseline characteristics

Reporting groups

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

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

| Reporting group values | A4: GT3 NC TN Grazoprevir+Uprifos buvir+Ruzasvir (8 weeks) | B4: GT3 NC TN MK-3682B (8 weeks) | B5: GT3 NC TN MK-3682B + RBV (8 weeks) |
|-------------------------------|--|----------------------------------|--|
| Number of subjects | 22 | 16 | 36 |
| Age, Customized | | | |
| Units: Subjects | | | |
| Less than 18 years | 0 | 0 | 0 |
| 18 to 35 years | 4 | 3 | 8 |
| 36 to 50 years | 12 | 4 | 11 |
| 51 to 64 years | 3 | 6 | 16 |
| Over 64 years | 3 | 3 | 1 |
| Sex: Female, Male | | | |
| Units: Subjects | | | |
| Female | 11 | 7 | 19 |
| Male | 11 | 9 | 17 |

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

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

| Reporting group values | B12: GT3 NC TE MK-3682B (16 weeks) | B13: GT3 C TN MK-3682B (12 weeks) | B14: GT3 C TN MK-3682B + RBV (12 weeks) |
|--------------------------------------|------------------------------------|-----------------------------------|---|
| Number of subjects | 16 | 13 | 16 |
| Age, Customized Units: Subjects | | | |
| Less than 18 years | 0 | 0 | 0 |
| 18 to 35 years | 0 | 0 | 0 |
| 36 to 50 years | 6 | 7 | 3 |
| 51 to 64 years | 9 | 4 | 13 |
| Over 64 years | 1 | 2 | 0 |
| Sex: Female, Male Units: Subjects | | | |
| Female | 5 | 3 | 5 |
| Male | 11 | 10 | 11 |

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

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

| Reporting group values | B22: GT6 NC TN MK-3682B (12 weeks) | Total | |
|-------------------------------|------------------------------------|-------|--|
| Number of subjects | 4 | 412 | |

| | | | |
|--------------------------------------|---|-----|--|
| Age, Customized Units: Subjects | | | |
| Less than 18 years | 0 | 0 | |
| 18 to 35 years | 0 | 49 | |
| 36 to 50 years | 1 | 150 | |
| 51 to 64 years | 3 | 194 | |
| Over 64 years | 0 | 19 | |
| Sex: Female, Male Units: Subjects | | | |
| Female | 2 | 179 | |
| Male | 2 | 233 | |

End points

End points reporting groups

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

| | |
|----------------------------|-------------------------------------|
| Subject analysis set title | A4+B4: GT3 NC TN MK-3682B (8 weeks) |
|----------------------------|-------------------------------------|

| | |
|---------------------------|--------------------|
| Subject analysis set type | Sub-group analysis |
|---------------------------|--------------------|

Subject analysis set description:

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

| | |
|----------------------------|--------------------------------------|
| Subject analysis set title | A4+ B4: GT3 NC TN MK-3682B (8 weeks) |
|----------------------------|--------------------------------------|

| | |
|---------------------------|--------------------|
| Subject analysis set type | Sub-group analysis |
|---------------------------|--------------------|

Subject analysis set description:

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

| | |
|----------------------------|-------------------------------------|
| Subject analysis set title | A4+B4: GT3 NC TN MK-3682B (8 weeks) |
|----------------------------|-------------------------------------|

| | |
|--|--|
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: | |
| In Part B, HCV GT3-infected NC TN participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. by mouth for 8 weeks. | |
| Subject analysis set title | Part C: GT3 NC TN: MK-3682B + RBV (16 weeks) |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

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

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

| | |
|-----------------|---|
| End point title | Percentage of HCV GT3-infected participants achieving Sustained Virologic Response at follow-up Week 12 (SVR12) ^{[1][2]} |
|-----------------|---|

End point description:

SVR12 is defined as HCV ribonucleic acid (RNA) less than the lower limit of quantification (<LLOQ, 15 IU/mL) 12 weeks after the end of all study therapy. A4+B4: GT3 NC TN MK-3682B (8 weeks) arm includes both participants from Part A and Part B who received equivalent dose of MK-3682B. Analysis population included HCV GT3 participants who received treatment and did not have major protocol deviations that may substantially affect the results of the SVR endpoints. Therefore, only GT3 treatment arms are presented in the table below.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Up to 20 weeks (Part A), up to 28 weeks (Part B)

Notes:

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

Justification: No statistical analyses were planned for this endpoint.

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

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

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

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

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

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

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

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

Statistical analyses

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

| | |
|-----------------|--|
| End point title | Number of participants experiencing an adverse event (AE) ^[3] |
|-----------------|--|

End point description:

An adverse event is defined as any untoward medical occurrence in a patient or clinical investigation participant administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment. Part C in the table below combines all (eight) participants from the four distinct arms of Part A who relapsed and were subsequently treated with MK-3682B + RBV for 16 weeks. Analysis population included all participants who received at least 1 dose of study drug, categorized according to the treatment actually received. A4+B4: GT3 NC TN MK-3682B (8 weeks) arm includes both participants from Part A and Part B who received equivalent dose of MK-3682B. Part C arm includes participants who relapsed following the completion of Part A therapy and received treatment during Part C.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Up to 40 weeks

Notes:

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

Justification: No statistical analyses were planned for this endpoint.

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

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

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

| End point values | B12: GT3 NC TE MK-3682B | B13: GT3 C TN MK-3682B (12 | B14: GT3 C TN MK-3682B + | B15: GT3 C TN MK-3682B (16 |
|------------------|----------------------------|-------------------------------|-----------------------------|-------------------------------|
|------------------|----------------------------|-------------------------------|-----------------------------|-------------------------------|

| | | | | |
|-----------------------------|-----------------|-----------------|-----------------|-----------------|
| | (16 weeks) | weeks) | RBV (12 weeks) | weeks) |
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 16 | 13 | 16 | 14 |
| Units: Participants | 13 | 9 | 14 | 12 |

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

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

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

An adverse event is defined as any untoward medical occurrence in a patient or clinical investigation participant administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment. Part C in the table below combines all (eight) participants from the four distinct arms of Part A who relapsed and were subsequently treated with MK-3682B + RBV for 16 weeks. Analysis population included all participants who received at least 1 dose of study drug, categorized according to the treatment actually received. A4+B4: GT3 NC TN MK-3682B (8 weeks) arm includes both participants from Part A and Part B who received equivalent dose of MK-3682B. Part C arm includes participants who relapsed following the completion of Part A therapy and received treatment during Part C.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Up to 16 weeks

Notes:

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

Justification: No statistical analyses were planned for this endpoint.

| | | | | |
|-----------------------------|--|---|--|---|
| End point values | A1: GT3 NC TN Grazoprevir+U prifosbuvir+Elb asvir (8 weeks) | A2: GT3 NC TN Grazoprevir+U prifosbuvir+Ru zasvir (8 weeks) | A3: GT3 NC TN Grazoprevir+U prifosbuvir+Elb asvir (8 weeks) | A4: GT3 NC TN Grazoprevir+U prifosbuvir+Ru zasvir (8 weeks) |
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 21 | 21 | 22 | 22 |
| Units: Participants | 0 | 0 | 0 | 0 |

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

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

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

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

| | | | | |
|-------------------------|---|--|-------------------------------------|---|
| End point values | B20: GT4 NC TN MK-3682B (8 weeks) | B22: GT6 NC TN MK-3682B (12 weeks) | A4+B4: GT3 NC TN MK- 3682B (8 | Part C: GT3 NC TN: MK-3682B + RBV (16 |
|-------------------------|---|--|-------------------------------------|---|

| | | | weeks) | weeks) |
|-----------------------------|-----------------|-----------------|----------------------|----------------------|
| Subject group type | Reporting group | Reporting group | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 7 | 4 | 38 | 8 |
| Units: Participants | 0 | 0 | 0 | 0 |

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to 40 weeks

Notes:

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

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

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

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

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

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

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

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

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

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

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 20.0 |
|--------------------|------|

Reporting groups

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

In Part A, participants received grazoprevir (100 mg) + uprifosbuvir (450 mg) + elbasvir (50 mg) q.d. by mouth for 8 weeks. After relapsing, participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. and RBV (weight-based dosing) b.i.d. by mouth for 16 weeks in Part C.

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

Reporting group description:

In Part A, participants received grazoprevir 100 mg + uprifosbuvir 450 mg + ruzasvir 60 mg q.d. by mouth for 8 weeks. After relapsing, participants received 2 MK-3682B FDC tablets (each containing grazoprevir 50 mg + uprifosbuvir 225 mg + ruzasvir 30 mg) q.d. and RBV (weight-based dosing) b.i.d. by mouth for 16 weeks in Part C.

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

Reporting group description:

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

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

Reporting group description:

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

| | |
|-----------------------|---------------------------------|
| Reporting group title | B6: GT3 NC TN MK-3682B (12 wks) |
|-----------------------|---------------------------------|

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

| | |
|-----------------------|--------------------------------|
| Reporting group title | B8: GT3 NC TE MK-3682B (8 wks) |
|-----------------------|--------------------------------|

Reporting group description:

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

| | |
|-----------------------|----------------------------------|
| Reporting group title | B10: GT3 NC TE MK-3682B (12 wks) |
|-----------------------|----------------------------------|

Reporting group description:

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

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

Reporting group description:

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

| | |
|-----------------------|----------------------------------|
| Reporting group title | B12: GT3 NC TE MK-3682B (16 wks) |
|-----------------------|----------------------------------|

Reporting group description:

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

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

Reporting group description:

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

| | |
|-----------------------|---------------------------------|
| Reporting group title | B13: GT3 C TN MK-3682B (12 wks) |
|-----------------------|---------------------------------|

Reporting group description:

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

| | |
|-----------------------|---------------------------------|
| Reporting group title | B15: GT3 C TN MK-3682B (16 wks) |
|-----------------------|---------------------------------|

Reporting group description:

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

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

Reporting group description:

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

| | |
|-----------------------|---------------------------------|
| Reporting group title | B16: GT3 C TE MK-3682B (12 wks) |
|-----------------------|---------------------------------|

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

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

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

| | wks) | | wks) |
|---|---------------|----------------|---------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 19 (5.26%) | 0 / 3 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Investigations | | | |
| Blood sodium decreased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Hepatocellular carcinoma | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Inflammatory pseudotumour | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lip and/or oral cavity cancer stage 0 | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Tendon rupture | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Coronary artery disease | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Cerebral haemorrhage | | | |

| | | | |
|---|---------------|----------------|---------------|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Migraine | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Keratitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 19 (5.26%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| Biliary colic | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Chronic obstructive pulmonary disease | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Alcohol abuse | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anxiety | | | |

| | | | |
|---|---------------|----------------|---------------|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mental status changes | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Pharyngeal abscess | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| 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+C: GT3 NC TN GZR+RZR+UPR450 (8 wks); MK- 3682B+RBV (16 wks) | A4: GT3 NC TN GZR+RZR+UPR450 (8 wks) | B4: GT3 NC TN MK- 3682B (8 wks) |
|--|--|--|------------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Investigations | | | |
| Blood sodium decreased | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 0 / 20 (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 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Hepatocellular carcinoma | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (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 |
| Inflammatory pseudotumour | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (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 |
| Lip and/or oral cavity cancer stage 0 | | | |

| | | | |
|---|---------------|----------------|----------------|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (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 |
| Injury, poisoning and procedural complications | | | |
| Tendon rupture | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (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 | | | |
| Coronary artery disease | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (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 |
| Nervous system disorders | | | |
| Cerebral haemorrhage | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (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 |
| Migraine | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (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 |
| Eye disorders | | | |
| Keratitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (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 |
| Gastrointestinal disorders | | | |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (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 |
| Hepatobiliary disorders | | | |
| Biliary colic | | | |

| | | | |
|--|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (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 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Chronic obstructive pulmonary disease | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (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 | | | |
| Alcohol abuse | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (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 |
| Anxiety | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 0 / 20 (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 |
| Mental status changes | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (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 | | | |
| Pharyngeal abscess | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (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 | B6: GT3 NC TN MK-3682B (12 wks) | B5: GT3 NC TN MK-3682B + RBV (8 wks) | B7: GT3 NC TN MK-3682B + RBV (12 wks) |
|--|--|---|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 1 / 36 (2.78%) | 1 / 35 (2.86%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Investigations | | | |
| Blood sodium decreased | | | |

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

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

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Pharyngeal abscess | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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

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

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 14 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Alcohol abuse | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 14 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anxiety | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 14 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mental status changes | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 14 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Pharyngeal abscess | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 14 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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

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

| | | | |
|--|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 15 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 15 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| Biliary colic | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 15 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Chronic obstructive pulmonary disease | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 15 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Alcohol abuse | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 15 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anxiety | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 15 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mental status changes | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 15 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Pharyngeal abscess | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 15 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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

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

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 16 (0.00%) | 1 / 15 (6.67%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anxiety | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 16 (0.00%) | 0 / 15 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mental status changes | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | 0 / 16 (0.00%) | 0 / 15 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Pharyngeal abscess | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 16 (0.00%) | 0 / 15 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | B17: GT3 C TE MK-3682B + RBV (12 wks) | B18: GT3 C TE MK-3682B (16 wks) | B20: GT4 NC TN MK-3682B (8 wks) |
|--|---------------------------------------|---------------------------------|---------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 2 / 14 (14.29%) | 2 / 20 (10.00%) | 0 / 7 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Investigations | | | |
| Blood sodium decreased | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Hepatocellular carcinoma | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Inflammatory pseudotumour | | | |

| | | | |
|---|----------------|----------------|---------------|
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lip and/or oral cavity cancer stage 0 | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Tendon rupture | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Coronary artery disease | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 1 / 20 (5.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Cerebral haemorrhage | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Migraine | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Keratitis | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain lower | | | |

| | | | |
|--|---------------------------------------|----------------------------------|---------------|
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| Biliary colic | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 1 / 20 (5.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Chronic obstructive pulmonary disease | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Alcohol abuse | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anxiety | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mental status changes | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Pharyngeal abscess | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| 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 | | | |
| | B19: GT3 C TE MK-3682B + RBV (16 wks) | B22: GT6 NC TN MK-3682B (12 wks) | |
| Total subjects affected by serious | | | |

| | | | |
|---|----------------|---------------|--|
| adverse events | | | |
| subjects affected / exposed | 1 / 25 (4.00%) | 0 / 4 (0.00%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |
| Investigations | | | |
| Blood sodium decreased | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Hepatocellular carcinoma | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inflammatory pseudotumour | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lip and/or oral cavity cancer stage 0 | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury, poisoning and procedural complications | | | |
| Tendon rupture | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |
| Coronary artery disease | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| Cerebral haemorrhage | | | |

| | | | |
|---|----------------|---------------|--|
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Migraine | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye disorders | | | |
| Keratitis | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Abdominal pain lower | | | |
| subjects affected / exposed | 1 / 25 (4.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Biliary colic | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Chronic obstructive pulmonary disease | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychiatric disorders | | | |
| Alcohol abuse | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anxiety | | | |

| | | | |
|---|----------------|---------------|--|
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mental status changes | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Pharyngeal abscess | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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|---|---|--------------------------------------|---|
| Non-serious adverse events | A2+C: GT3 NC TN GZR+RZR+UPR300 (8 wks); MK-3682B+RBV (16 wks) | A3: GT3 NC TN EBR+GZR+UPR450 (8 wks) | A3+C: GT3 NC TN EBR+GZR+UPR450 (8 wks); MK-3682B+RBV (16 wks) |
| Total subjects affected by non-serious adverse events subjects affected / exposed | 1 / 1 (100.00%) | 13 / 19 (68.42%) | 3 / 3 (100.00%) |

| | | | |
|--|---------------|-----------------|----------------|
| Vascular disorders | | | |
| Arteriosclerosis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flushing | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hot flush | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 19 (5.26%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Chest discomfort | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chest pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Energy increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 4 / 19 (21.05%) | 1 / 3 (33.33%) |
| occurrences (all) | 0 | 4 | 1 |
| Feeling abnormal | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 19 (5.26%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Feeling cold | | | |

| | | | |
|--|---------------|----------------|---------------|
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 19 (5.26%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Feeling hot | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Feeling jittery | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza like illness | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 19 (5.26%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Local swelling | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vessel puncture site pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 19 (5.26%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Immune system disorders | | | |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Breast tenderness | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erectile dysfunction | | | |

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|---|-----------------|-----------------|---------------|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vulval haematoma | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Chronic obstructive pulmonary disease | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cough | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 2 / 19 (10.53%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Dry throat | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysphonia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemoptysis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 19 (5.26%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nasal discomfort | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oropharyngeal pain | | | |

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| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paranasal sinus discomfort | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Productive cough | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis allergic | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus congestion | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Throat irritation | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Affect lability | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anxiety | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 19 (5.26%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Depressed mood | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 19 (5.26%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Depression | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Emotional disorder | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|-----------------|-----------------|----------------|
| Insomnia | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 2 / 19 (10.53%) | 0 / 3 (0.00%) |
| occurrences (all) | 2 | 2 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 19 (5.26%) | 1 / 3 (33.33%) |
| occurrences (all) | 0 | 1 | 1 |
| Panic attack | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sleep disorder | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tearfulness | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Amylase increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bacterial test positive | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood creatinine increased | | | |

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

| | | | |
|-----------------------------|---------------|----------------|---------------|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bone contusion | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Clavicle fracture | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 19 (5.26%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Foot fracture | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Foreign body | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ligament sprain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle strain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rib fracture | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tendon injury | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac disorders | | | |

| | | | |
|-----------------------------|-----------------|-----------------|---------------|
| Arrhythmia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bundle branch block right | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Palpitations | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus tachycardia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tachycardia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Disturbance in attention | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 2 / 19 (10.53%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Dizziness | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 1 / 19 (5.26%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Dizziness postural | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysgeusia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyskinesia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache | | | |

| | | | |
|---|-----------------|-----------------|----------------|
| subjects affected / exposed | 1 / 1 (100.00%) | 5 / 19 (26.32%) | 0 / 3 (0.00%) |
| occurrences (all) | 2 | 8 | 0 |
| Hypersomnia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lethargy | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 1 / 19 (5.26%) | 1 / 3 (33.33%) |
| occurrences (all) | 1 | 1 | 1 |
| Memory impairment | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Migraine | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Parosmia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Poor quality sleep | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sciatica | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Somnolence | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tension headache | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|-----------------------------|---------------|----------------|---------------|
| Haemolysis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemolytic anaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymph node pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear and labyrinth disorders | | | |
| Tinnitus | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 19 (5.26%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vertigo | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye disorders | | | |
| Dry eye | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ocular discomfort | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pinguecula | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vision blurred | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Visual impairment | | | |

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|--|----------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Abdominal distension subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Abdominal pain subjects affected / exposed occurrences (all) | 1 / 1 (100.00%) 1 | 0 / 19 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Abdominal pain upper subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 19 (5.26%) 1 | 0 / 3 (0.00%) 0 |
| Aphthous ulcer subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Constipation subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 19 (5.26%) 1 | 2 / 3 (66.67%) 2 |
| Dental caries subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Diarrhoea subjects affected / exposed occurrences (all) | 1 / 1 (100.00%) 1 | 0 / 19 (0.00%) 0 | 1 / 3 (33.33%) 1 |
| Diverticulum subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Dry mouth subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 19 (5.26%) 1 | 0 / 3 (0.00%) 0 |
| Dyspepsia subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 19 (5.26%) 1 | 0 / 3 (0.00%) 0 |

| | | | |
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| Faeces soft | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 19 (5.26%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Frequent bowel movements | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastritis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 19 (5.26%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hiatus hernia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infrequent bowel movements | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritable bowel syndrome | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip dry | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 1 / 3 (33.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Nausea | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 5 / 19 (26.32%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 6 | 0 |
| Oral pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 19 (5.26%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Paraesthesia oral | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

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| Salivary hypersecretion | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tongue ulceration | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 19 (5.26%) | 1 / 3 (33.33%) |
| occurrences (all) | 0 | 1 | 1 |
| Skin and subcutaneous tissue disorders | | | |
| Acne | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Actinic keratosis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Alopecia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 1 / 3 (33.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Dermatitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis contact | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry skin | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ecchymosis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eczema | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 19 (5.26%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Erythema | | | |

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| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 19 (5.26%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperkeratosis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Macule | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Night sweats | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 19 (5.26%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Photosensitivity reaction | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 19 (5.26%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rash | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 0 / 19 (0.00%) | 2 / 3 (66.67%) |
| occurrences (all) | 1 | 0 | 2 |
| Rash erythematous | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin discolouration | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 1 / 3 (33.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin lesion | | | |

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

| | | | |
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| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle spasms | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 19 (5.26%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Plantar fasciitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhabdomyolysis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Acute sinusitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|-----------------------------------|---------------|----------------|----------------|
| Cellulitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cystitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Genital herpes | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingivitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes simplex | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hordeolum | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infected dermal cyst | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 1 / 3 (33.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
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| Oral herpes | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periodontitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngitis streptococcal | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth abscess | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 19 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|----------------------|----------------------|---------------------|
| Upper respiratory tract infection subjects affected / exposed occurrences (all) | 1 / 1 (100.00%) 1 | 0 / 19 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Urinary tract infection subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 19 (5.26%) 1 | 0 / 3 (0.00%) 0 |
| Viral infection subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Viral upper respiratory tract infection subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 2 / 19 (10.53%) 3 | 1 / 3 (33.33%) 2 |
| Wound infection staphylococcal subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 19 (5.26%) 1 | 0 / 3 (0.00%) 0 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 19 (5.26%) 1 | 0 / 3 (0.00%) 0 |
| Gout subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Hyperamylasaemia subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 19 (5.26%) 1 | 0 / 3 (0.00%) 0 |
| Hyperglycaemia subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Hyperlipasaemia subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 19 (5.26%) 1 | 0 / 3 (0.00%) 0 |
| Hyperlipidaemia subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Hypokalaemia | | | |

| | | | |
|--|--------------------|---------------------|--------------------|
| subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Increased appetite subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 19 (5.26%) 1 | 0 / 3 (0.00%) 0 |
| Vitamin D deficiency subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 3 (0.00%) 0 |

| Non-serious adverse events | A4+C: GT3 NC TN GZR+RZR+UPR450 (8 wks); MK- 3682B+RBV (16 wks) | A4: GT3 NC TN GZR+RZR+UPR450 (8 wks) | B4: GT3 NC TN MK- 3682B (8 wks) |
|---|--|--|------------------------------------|
| Total subjects affected by non-serious adverse events subjects affected / exposed | 2 / 2 (100.00%) | 16 / 20 (80.00%) | 9 / 16 (56.25%) |
| Vascular disorders | | | |
| Arteriosclerosis subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Flushing subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Hot flush subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Hypertension subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| General disorders and administration site conditions | | | |
| Asthenia subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 1 / 20 (5.00%) 1 | 0 / 16 (0.00%) 0 |
| Chest discomfort subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Chest pain | | | |

| | | | |
|-------------------------------|----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Energy increased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 4 / 20 (20.00%) | 2 / 16 (12.50%) |
| occurrences (all) | 2 | 4 | 2 |
| Feeling abnormal | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Feeling cold | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Feeling hot | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Feeling jittery | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza like illness | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Local swelling | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |

| | | | |
|--|--------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Vessel puncture site pain subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Reproductive system and breast disorders Breast tenderness subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Erectile dysfunction subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Vulval haematoma subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders Chronic obstructive pulmonary disease subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Cough subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Dry throat subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Dysphonia subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Dyspnoea subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| Dyspnoea exertional | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Epistaxis | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Haemoptysis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal discomfort | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Paranasal sinus discomfort | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Productive cough | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis allergic | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus congestion | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Throat irritation | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Affect lability | | | |

| | | | |
|------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anxiety | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Depressed mood | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 20 (5.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 1 | 1 |
| Depression | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Emotional disorder | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Insomnia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 20 (5.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Panic attack | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Sleep disorder | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 20 (5.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Tearfulness | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 20 (5.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Amylase increased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|---------------|----------------|----------------|
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bacterial test positive | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood creatinine increased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood potassium increased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood urine present | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemoglobin decreased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Heart rate increased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lipase increased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Protein urine present | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Transaminases increased | | | |

| | | | |
|--|--------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| White blood cells urine positive subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Injury, poisoning and procedural complications | | | |
| Accidental overdose subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 1 / 20 (5.00%) 1 | 0 / 16 (0.00%) 0 |
| Arthropod bite subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Arthropod sting subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Bone contusion subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Clavicle fracture subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Contusion subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Fall subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Foot fracture subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Foreign body subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Ligament sprain | | | |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle strain | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rib fracture | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tendon injury | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac disorders | | | |
| Arrhythmia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Bundle branch block right | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Palpitations | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus tachycardia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tachycardia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Disturbance in attention | | | |

| | | | |
|-----------------------------|----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dizziness | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 1 / 20 (5.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Dizziness postural | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysgeusia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 20 (5.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dyskinesia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 5 / 20 (25.00%) | 5 / 16 (31.25%) |
| occurrences (all) | 1 | 6 | 6 |
| Hypersomnia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lethargy | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 20 (5.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Memory impairment | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 20 (5.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Migraine | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Parosmia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Poor quality sleep | | | |

| | | | |
|---|--------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Sciatica subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Somnolence subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Tension headache subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Haemolysis subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Haemolytic anaemia subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Lymph node pain subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Lymphadenopathy subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Ear and labyrinth disorders Tinnitus subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 1 / 20 (5.00%) 1 | 0 / 16 (0.00%) 0 |
| Vertigo subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Eye disorders | | | |

| | | | |
|-----------------------------|---------------|----------------|----------------|
| Dry eye | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ocular discomfort | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pinguecula | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Vision blurred | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Visual impairment | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 20 (5.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Abdominal distension | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 20 (5.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 20 (5.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 1 | 1 |
| Aphthous ulcer | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Constipation | | | |

| | | | |
|---------------------------------|---------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 20 (5.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dental caries | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 20 (15.00%) | 2 / 16 (12.50%) |
| occurrences (all) | 0 | 3 | 2 |
| Diverticulum | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry mouth | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspepsia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 20 (5.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Faeces soft | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 20 (5.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Frequent bowel movements | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastritis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Gastroesophageal reflux disease | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hiatus hernia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infrequent bowel movements | | | |

| | | | |
|---|----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritable bowel syndrome | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip dry | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 6 / 20 (30.00%) | 2 / 16 (12.50%) |
| occurrences (all) | 0 | 6 | 2 |
| Oral pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paraesthesia oral | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Salivary hypersecretion | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tongue ulceration | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 20 (15.00%) | 2 / 16 (12.50%) |
| occurrences (all) | 0 | 3 | 3 |
| Skin and subcutaneous tissue disorders | | | |
| Acne | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Actinic keratosis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Alopecia | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 1 / 20 (5.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |

| | | | |
|---|--|--|--|
| <p> Dermatitis subjects affected / exposed occurrences (all) </p> | <p> 0 / 2 (0.00%) 0 </p> | <p> 0 / 20 (0.00%) 0 </p> | <p> 0 / 16 (0.00%) 0 </p> |
| <p> Dermatitis contact subjects affected / exposed occurrences (all) </p> | <p> 0 / 2 (0.00%) 0 </p> | <p> 0 / 20 (0.00%) 0 </p> | <p> 0 / 16 (0.00%) 0 </p> |
| <p> Dry skin subjects affected / exposed occurrences (all) </p> | <p> 1 / 2 (50.00%) 1 </p> | <p> 1 / 20 (5.00%) 1 </p> | <p> 0 / 16 (0.00%) 0 </p> |
| <p> Ecchymosis subjects affected / exposed occurrences (all) </p> | <p> 0 / 2 (0.00%) 0 </p> | <p> 0 / 20 (0.00%) 0 </p> | <p> 0 / 16 (0.00%) 0 </p> |
| <p> Eczema subjects affected / exposed occurrences (all) </p> | <p> 0 / 2 (0.00%) 0 </p> | <p> 0 / 20 (0.00%) 0 </p> | <p> 0 / 16 (0.00%) 0 </p> |
| <p> Erythema subjects affected / exposed occurrences (all) </p> | <p> 0 / 2 (0.00%) 0 </p> | <p> 0 / 20 (0.00%) 0 </p> | <p> 0 / 16 (0.00%) 0 </p> |
| <p> Hyperhidrosis subjects affected / exposed occurrences (all) </p> | <p> 0 / 2 (0.00%) 0 </p> | <p> 0 / 20 (0.00%) 0 </p> | <p> 0 / 16 (0.00%) 0 </p> |
| <p> Hyperkeratosis subjects affected / exposed occurrences (all) </p> | <p> 0 / 2 (0.00%) 0 </p> | <p> 0 / 20 (0.00%) 0 </p> | <p> 0 / 16 (0.00%) 0 </p> |
| <p> Macule subjects affected / exposed occurrences (all) </p> | <p> 0 / 2 (0.00%) 0 </p> | <p> 0 / 20 (0.00%) 0 </p> | <p> 0 / 16 (0.00%) 0 </p> |
| <p> Night sweats subjects affected / exposed occurrences (all) </p> | <p> 0 / 2 (0.00%) 0 </p> | <p> 0 / 20 (0.00%) 0 </p> | <p> 0 / 16 (0.00%) 0 </p> |
| <p> Photosensitivity reaction subjects affected / exposed occurrences (all) </p> | <p> 0 / 2 (0.00%) 0 </p> | <p> 0 / 20 (0.00%) 0 </p> | <p> 0 / 16 (0.00%) 0 </p> |
| <p> Pruritus subjects affected / exposed occurrences (all) </p> | <p> 0 / 2 (0.00%) 0 </p> | <p> 1 / 20 (5.00%) 1 </p> | <p> 1 / 16 (6.25%) 1 </p> |

| | | | |
|---|---------------|----------------|----------------|
| Rash | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash erythematous | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin discolouration | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin lesion | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nephropathy | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal cyst | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Ankylosing spondylitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthralgia | | | |

| | | | |
|----------------------------------|---------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 20 (10.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Back pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 2 / 16 (12.50%) |
| occurrences (all) | 0 | 0 | 2 |
| Fibromyalgia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Groin pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intervertebral disc degeneration | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint swelling | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle spasms | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 20 (5.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain in extremity | | | |

| | | | |
|------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 20 (5.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Plantar fasciitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhabdomyolysis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Acute sinusitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cystitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Genital herpes | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingivitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes simplex | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|-----------------------------------|---------------|----------------|----------------|
| Hordeolum | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infected dermal cyst | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral herpes | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periodontitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 20 (5.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pharyngitis streptococcal | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|---------------------|----------------------|----------------------|
| Respiratory tract infection subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Rhinitis subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 1 / 20 (5.00%) 1 | 0 / 16 (0.00%) 0 |
| Sinusitis subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Tooth abscess subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Tooth infection subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Upper respiratory tract infection subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 1 / 20 (5.00%) 1 | 1 / 16 (6.25%) 1 |
| Urinary tract infection subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Viral infection subjects affected / exposed occurrences (all) | 1 / 2 (50.00%) 1 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Viral upper respiratory tract infection subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 2 / 20 (10.00%) 3 | 2 / 16 (12.50%) 2 |
| Wound infection staphylococcal subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 16 (0.00%) 0 |
| Gout | | | |

| | | | |
|-----------------------------|---------------|----------------|----------------|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperamylasaemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperglycaemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperlipasaemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperlipidaemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypokalaemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Increased appetite | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitamin D deficiency | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 20 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

| Non-serious adverse events | B17: GT3 C TE MK-3682B + RBV (12 wks) | B18: GT3 C TE MK-3682B (16 wks) | B20: GT4 NC TN MK-3682B (8 wks) |
|---|---------------------------------------|---------------------------------|---------------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 11 / 14 (78.57%) | 15 / 20 (75.00%) | 3 / 7 (42.86%) |
| Vascular disorders | | | |
| Arteriosclerosis | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flushing | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hot flush | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 3 / 14 (21.43%) | 1 / 20 (5.00%) | 1 / 7 (14.29%) |
| occurrences (all) | 3 | 2 | 1 |
| Chest discomfort | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chest pain | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | 1 / 20 (5.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Chills | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Energy increased | | | |

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

| | | | |
|---|---------------------|----------------------|--------------------|
| Seasonal allergy subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Reproductive system and breast disorders | | | |
| Breast tenderness subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Erectile dysfunction subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Vulval haematoma subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Chronic obstructive pulmonary disease subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Cough subjects affected / exposed occurrences (all) | 1 / 14 (7.14%) 1 | 3 / 20 (15.00%) 3 | 0 / 7 (0.00%) 0 |
| Dry throat subjects affected / exposed occurrences (all) | 1 / 14 (7.14%) 1 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Dysphonia subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Dyspnoea subjects affected / exposed occurrences (all) | 1 / 14 (7.14%) 1 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Dyspnoea exertional subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Epistaxis subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |

| | | | |
|-----------------------------|----------------|----------------|---------------|
| Haemoptysis | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal discomfort | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paranasal sinus discomfort | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Productive cough | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis allergic | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus congestion | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 1 / 20 (5.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Throat irritation | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Affect lability | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anxiety | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Depressed mood | | | |

| | | | |
|--------------------------------------|-----------------|-----------------|---------------|
| subjects affected / exposed | 1 / 14 (7.14%) | 2 / 20 (10.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Depression | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Emotional disorder | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Insomnia | | | |
| subjects affected / exposed | 2 / 14 (14.29%) | 1 / 20 (5.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 1 / 20 (5.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Panic attack | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sleep disorder | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 1 / 20 (5.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Tearfulness | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Amylase increased | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bacterial test positive | | | |

| | | | |
|--|----------------|----------------|---------------|
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood creatinine increased | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood potassium increased | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood urine present | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemoglobin decreased | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Heart rate increased | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lipase increased | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Protein urine present | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Transaminases increased | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| White blood cells urine positive | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|----------------|----------------|---------------|
| Injury, poisoning and procedural complications | | | |
| Accidental overdose | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Arthropod bite | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Arthropod sting | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bone contusion | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Clavicle fracture | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 1 / 20 (5.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Fall | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Foot fracture | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Foreign body | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ligament sprain | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle strain | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rib fracture | | | |

| | | | |
|---|----------------------|----------------------|--------------------|
| subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 1 / 20 (5.00%) 1 | 0 / 7 (0.00%) 0 |
| Tendon injury subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Thermal burn subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Cardiac disorders | | | |
| Arrhythmia subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Atrial fibrillation subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Bundle branch block right subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Palpitations subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 1 / 20 (5.00%) 1 | 0 / 7 (0.00%) 0 |
| Sinus tachycardia subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Tachycardia subjects affected / exposed occurrences (all) | 1 / 14 (7.14%) 1 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Nervous system disorders | | | |
| Disturbance in attention subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 2 / 20 (10.00%) 2 | 0 / 7 (0.00%) 0 |
| Dizziness subjects affected / exposed occurrences (all) | 2 / 14 (14.29%) 2 | 1 / 20 (5.00%) 1 | 0 / 7 (0.00%) 0 |
| Dizziness postural | | | |

| | | | |
|-----------------------------|-----------------|-----------------|----------------|
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysgeusia | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyskinesia | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache | | | |
| subjects affected / exposed | 2 / 14 (14.29%) | 3 / 20 (15.00%) | 1 / 7 (14.29%) |
| occurrences (all) | 3 | 3 | 1 |
| Hypersomnia | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lethargy | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Memory impairment | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Migraine | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Paraesthesia | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Parosmia | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Poor quality sleep | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sciatica | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Somnolence | | | |

| | | | |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Tension headache subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Haemolysis subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Haemolytic anaemia subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Lymph node pain subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Lymphadenopathy subjects affected / exposed occurrences (all) | 1 / 14 (7.14%) 1 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Ear and labyrinth disorders | | | |
| Tinnitus subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 1 / 7 (14.29%) 1 |
| Vertigo subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Eye disorders | | | |
| Dry eye subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Eye pain subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Ocular discomfort | | | |

| | | | |
|-----------------------------|-----------------|-----------------|----------------|
| subjects affected / exposed | 1 / 14 (7.14%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pinguecula | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vision blurred | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Visual impairment | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Abdominal distension | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 1 / 20 (5.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 3 / 20 (15.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 2 / 14 (14.29%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Aphthous ulcer | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Constipation | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | 0 / 20 (0.00%) | 1 / 7 (14.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Dental caries | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | 1 / 20 (5.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |

| | | | |
|----------------------------------|-----------------|----------------|---------------|
| Diverticulum | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry mouth | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dyspepsia | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Faeces soft | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 2 / 14 (14.29%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Frequent bowel movements | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastritis | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hiatus hernia | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infrequent bowel movements | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritable bowel syndrome | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip dry | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|-----------------|-----------------|----------------|
| Nausea | | | |
| subjects affected / exposed | 2 / 14 (14.29%) | 2 / 20 (10.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 3 | 2 | 0 |
| Oral pain | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paraesthesia oral | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Salivary hypersecretion | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tongue ulceration | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Acne | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Actinic keratosis | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Alopecia | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis contact | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry skin | | | |

| | | | |
|-----------------------------|-----------------|----------------|---------------|
| subjects affected / exposed | 0 / 14 (0.00%) | 1 / 20 (5.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Ecchymosis | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eczema | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperkeratosis | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Macule | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Night sweats | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Photosensitivity reaction | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 1 / 20 (5.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | 1 / 20 (5.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Rash | | | |
| subjects affected / exposed | 2 / 14 (14.29%) | 1 / 20 (5.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 3 | 3 | 0 |
| Rash erythematous | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rash macular | | | |

| | | | |
|---|----------------|-----------------|----------------|
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin discolouration | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin lesion | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nephropathy | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal cyst | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Ankylosing spondylitis | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 1 / 20 (5.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Back pain | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | 3 / 20 (15.00%) | 1 / 7 (14.29%) |
| occurrences (all) | 1 | 3 | 1 |
| Fibromyalgia | | | |

| | | | |
|----------------------------------|----------------|----------------|---------------|
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Groin pain | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intervertebral disc degeneration | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint swelling | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Muscle spasms | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 1 / 20 (5.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 1 / 20 (5.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Plantar fasciitis | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhabdomyolysis | | | |

| | | | |
|--|---------------------|---------------------|--------------------|
| subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Infections and infestations | | | |
| Acute sinusitis | | | |
| subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Bronchitis | | | |
| subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Cellulitis | | | |
| subjects affected / exposed occurrences (all) | 1 / 14 (7.14%) 1 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Cystitis | | | |
| subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Ear infection | | | |
| subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 1 / 20 (5.00%) 1 | 0 / 7 (0.00%) 0 |
| Gastroenteritis | | | |
| subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Genital herpes | | | |
| subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Gingivitis | | | |
| subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Herpes simplex | | | |
| subjects affected / exposed occurrences (all) | 1 / 14 (7.14%) 1 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Hordeolum | | | |
| subjects affected / exposed occurrences (all) | 1 / 14 (7.14%) 1 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Infected dermal cyst | | | |
| subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 7 (0.00%) 0 |

| | | | |
|-----------------------------------|----------------|----------------|---------------|
| Influenza | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 1 / 20 (5.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral herpes | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periodontitis | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngitis streptococcal | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|----------------|---------------|
| Sinusitis | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth abscess | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth infection | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 1 / 20 (5.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 2 / 14 (14.29%) | 1 / 20 (5.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Wound infection staphylococcal | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite | | | |
| subjects affected / exposed | 2 / 14 (14.29%) | 1 / 20 (5.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Gout | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperamylasaemia | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperglycaemia | | | |

| | | | |
|-----------------------------|----------------|-----------------|---------------|
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperlipasaemia | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperlipidaemia | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypokalaemia | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Increased appetite | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 0 / 20 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitamin D deficiency | | | |
| subjects affected / exposed | 0 / 14 (0.00%) | 2 / 20 (10.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |

| Non-serious adverse events | B19: GT3 C TE MK-3682B + RBV (16 wks) | B22: GT6 NC TN MK-3682B (12 wks) | |
|---|---------------------------------------|----------------------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 21 / 25 (84.00%) | 3 / 4 (75.00%) | |
| Vascular disorders | | | |
| Arteriosclerosis | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Flushing | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Hot flush | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Hypertension | | | |
| subjects affected / exposed | 2 / 25 (8.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| General disorders and administration site conditions | | | |

| | | |
|-----------------------------|-----------------|---------------|
| Asthenia | | |
| subjects affected / exposed | 2 / 25 (8.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 2 | 0 |
| Chest discomfort | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Chest pain | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Chills | | |
| subjects affected / exposed | 2 / 25 (8.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 2 | 0 |
| Energy increased | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Fatigue | | |
| subjects affected / exposed | 9 / 25 (36.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 10 | 0 |
| Feeling abnormal | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Feeling cold | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Feeling hot | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Feeling jittery | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Influenza like illness | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Local swelling | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |

| | | | |
|--|----------------------|--------------------|--|
| Malaise subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Pain subjects affected / exposed occurrences (all) | 1 / 25 (4.00%) 1 | 0 / 4 (0.00%) 0 | |
| Pyrexia subjects affected / exposed occurrences (all) | 2 / 25 (8.00%) 2 | 0 / 4 (0.00%) 0 | |
| Vessel puncture site pain subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Reproductive system and breast disorders Breast tenderness subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Erectile dysfunction subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Vulval haematoma subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Respiratory, thoracic and mediastinal disorders Chronic obstructive pulmonary disease subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Cough subjects affected / exposed occurrences (all) | 3 / 25 (12.00%) 3 | 0 / 4 (0.00%) 0 | |
| Dry throat | | | |

| | | |
|-----------------------------|----------------|----------------|
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Dysphonia | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Dyspnoea | | |
| subjects affected / exposed | 2 / 25 (8.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 2 | 0 |
| Dyspnoea exertional | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Epistaxis | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Haemoptysis | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Nasal discomfort | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Oropharyngeal pain | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Paranasal sinus discomfort | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Productive cough | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Rhinitis allergic | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 1 |
| Rhinorrhoea | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Sinus congestion | | |

| | | | |
|-----------------------------|----------------|---------------|--|
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Throat irritation | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Psychiatric disorders | | | |
| Affect lability | | | |
| subjects affected / exposed | 1 / 25 (4.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Anxiety | | | |
| subjects affected / exposed | 1 / 25 (4.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Depressed mood | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Depression | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Emotional disorder | | | |
| subjects affected / exposed | 1 / 25 (4.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Insomnia | | | |
| subjects affected / exposed | 1 / 25 (4.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Irritability | | | |
| subjects affected / exposed | 2 / 25 (8.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Panic attack | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Sleep disorder | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Tearfulness | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |

| | | | |
|--|----------------|---------------|--|
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Amylase increased | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Bacterial test positive | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Blood creatinine increased | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Blood potassium increased | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Blood urine present | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Haemoglobin decreased | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Heart rate increased | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Lipase increased | | | |

| | | | |
|--|----------------------|---------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Protein urine present subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Transaminases increased subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| White blood cells urine positive subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Injury, poisoning and procedural complications | | | |
| Accidental overdose subjects affected / exposed occurrences (all) | 3 / 25 (12.00%) 4 | 0 / 4 (0.00%) 0 | |
| Arthropod bite subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Arthropod sting subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Bone contusion subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 1 / 4 (25.00%) 1 | |
| Clavicle fracture subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Contusion subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 1 / 4 (25.00%) 1 | |
| Fall subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Foot fracture | | | |

| | | | |
|-----------------------------|----------------|----------------|--|
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Foreign body | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Ligament sprain | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Muscle strain | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Rib fracture | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 1 / 4 (25.00%) | |
| occurrences (all) | 0 | 1 | |
| Tendon injury | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Cardiac disorders | | | |
| Arrhythmia | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 1 / 25 (4.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Bundle branch block right | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Palpitations | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Sinus tachycardia | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |

| | | | |
|-----------------------------|-----------------|----------------|--|
| Tachycardia | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Nervous system disorders | | | |
| Disturbance in attention | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Dizziness | | | |
| subjects affected / exposed | 1 / 25 (4.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Dizziness postural | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Dysgeusia | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Dyskinesia | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Headache | | | |
| subjects affected / exposed | 9 / 25 (36.00%) | 2 / 4 (50.00%) | |
| occurrences (all) | 11 | 2 | |
| Hypersomnia | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Lethargy | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Memory impairment | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Migraine | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Paraesthesia | | | |

| | | | |
|--------------------------------------|----------------|---------------|--|
| subjects affected / exposed | 1 / 25 (4.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Parosmia | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Poor quality sleep | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Sciatica | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Somnolence | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Tension headache | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Haemolysis | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Haemolytic anaemia | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Lymph node pain | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Ear and labyrinth disorders | | | |
| Tinnitus | | | |

| | | | |
|--|----------------------|---------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Vertigo subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Eye disorders | | | |
| Dry eye subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Eye pain subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 1 / 4 (25.00%) 1 | |
| Ocular discomfort subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Pinguecula subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Vision blurred subjects affected / exposed occurrences (all) | 1 / 25 (4.00%) 1 | 0 / 4 (0.00%) 0 | |
| Visual impairment subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Gastrointestinal disorders | | | |
| Abdominal discomfort subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Abdominal distension subjects affected / exposed occurrences (all) | 3 / 25 (12.00%) 3 | 0 / 4 (0.00%) 0 | |
| Abdominal pain subjects affected / exposed occurrences (all) | 1 / 25 (4.00%) 1 | 0 / 4 (0.00%) 0 | |
| Abdominal pain upper | | | |

| | | |
|---------------------------------|----------------|---------------|
| subjects affected / exposed | 1 / 25 (4.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 |
| Aphthous ulcer | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Constipation | | |
| subjects affected / exposed | 2 / 25 (8.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 2 | 0 |
| Dental caries | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Diarrhoea | | |
| subjects affected / exposed | 1 / 25 (4.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 2 | 0 |
| Diverticulum | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Dry mouth | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Dyspepsia | | |
| subjects affected / exposed | 1 / 25 (4.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 |
| Faeces soft | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Flatulence | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Frequent bowel movements | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Gastritis | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Gastroesophageal reflux disease | | |

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|--|-----------------|---------------|--|
| subjects affected / exposed | 1 / 25 (4.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Hiatus hernia | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Infrequent bowel movements | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Irritable bowel syndrome | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Lip dry | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Nausea | | | |
| subjects affected / exposed | 4 / 25 (16.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 5 | 0 | |
| Oral pain | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Paraesthesia oral | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Salivary hypersecretion | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Tongue ulceration | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Vomiting | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Acne | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |

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|-----------------------------|----------------|----------------|
| Actinic keratosis | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Alopecia | | |
| subjects affected / exposed | 1 / 25 (4.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 |
| Dermatitis | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Dermatitis contact | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Dry skin | | |
| subjects affected / exposed | 2 / 25 (8.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 2 | 0 |
| Ecchymosis | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Eczema | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Erythema | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Hyperhidrosis | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Hyperkeratosis | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 1 |
| Macule | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Night sweats | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |

| | | | |
|---|----------------------|---------------------|--|
| Photosensitivity reaction subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Pruritus subjects affected / exposed occurrences (all) | 5 / 25 (20.00%) 5 | 0 / 4 (0.00%) 0 | |
| Rash subjects affected / exposed occurrences (all) | 1 / 25 (4.00%) 1 | 0 / 4 (0.00%) 0 | |
| Rash erythematous subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Rash macular subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 1 / 4 (25.00%) 1 | |
| Rash maculo-papular subjects affected / exposed occurrences (all) | 1 / 25 (4.00%) 1 | 0 / 4 (0.00%) 0 | |
| Skin discolouration subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Skin lesion subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Urticaria subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Renal and urinary disorders | | | |
| Nephrolithiasis subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Nephropathy subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Renal cyst | | | |

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| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Ankylosing spondylitis | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Arthralgia | | | |
| subjects affected / exposed | 2 / 25 (8.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Back pain | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 1 / 4 (25.00%) | |
| occurrences (all) | 0 | 1 | |
| Fibromyalgia | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Groin pain | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Intervertebral disc degeneration | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Joint swelling | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Muscle spasms | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Musculoskeletal stiffness | | | |

| | | | |
|--|---------------------|---------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Myalgia | | | |
| subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Neck pain | | | |
| subjects affected / exposed occurrences (all) | 1 / 25 (4.00%) 1 | 1 / 4 (25.00%) 1 | |
| Pain in extremity | | | |
| subjects affected / exposed occurrences (all) | 1 / 25 (4.00%) 1 | 0 / 4 (0.00%) 0 | |
| Plantar fasciitis | | | |
| subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Rhabdomyolysis | | | |
| subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Infections and infestations | | | |
| Acute sinusitis | | | |
| subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Bronchitis | | | |
| subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Cellulitis | | | |
| subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Cystitis | | | |
| subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Ear infection | | | |
| subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Gastroenteritis | | | |
| subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |

| | | |
|-----------------------------------|----------------|---------------|
| Genital herpes | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Gingivitis | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Herpes simplex | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Hordeolum | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Infected dermal cyst | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Influenza | | |
| subjects affected / exposed | 1 / 25 (4.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 |
| Lower respiratory tract infection | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Nasopharyngitis | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Oral herpes | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Otitis media | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Paronychia | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Periodontitis | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |

| | | |
|---|----------------|----------------|
| Pharyngitis | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Pharyngitis streptococcal | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Pneumonia | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Respiratory tract infection | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Rhinitis | | |
| subjects affected / exposed | 2 / 25 (8.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 3 | 0 |
| Sinusitis | | |
| subjects affected / exposed | 1 / 25 (4.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 |
| Tooth abscess | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Tooth infection | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Upper respiratory tract infection | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 1 |
| Urinary tract infection | | |
| subjects affected / exposed | 1 / 25 (4.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 1 | 1 |
| Viral infection | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| Viral upper respiratory tract infection | | |
| subjects affected / exposed | 2 / 25 (8.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 2 | 0 |

| | | | |
|--|----------------------|--------------------|--|
| Wound infection staphylococcal subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Metabolism and nutrition disorders | | | |
| Decreased appetite subjects affected / exposed occurrences (all) | 3 / 25 (12.00%) 3 | 0 / 4 (0.00%) 0 | |
| Gout subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Hyperamylasaemia subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Hyperglycaemia subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Hyperlipasaemia subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Hyperlipidaemia subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Hypokalaemia subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Increased appetite subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Vitamin D deficiency subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 4 (0.00%) 0 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

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

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported