



Clinical trial results:

A Master Protocol to Investigate the Efficacy and Safety of Tirzepatide Once Weekly in Participants who have Obstructive Sleep Apnea and Obesity: A Randomized, Double-Blind, Placebo-Controlled Trial (SURMOUNT-OSA)

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2021-004552-41 |
| Trial protocol | CZ |
| Global end of trial date | 29 March 2024 |

Results information

| | |
|--------------------------------|---|
| Result version number | v2 (current) |
| This version publication date | 30 April 2025 |
| First version publication date | 27 March 2025 |
| Version creation reason | <ul style="list-style-type: none">• Correction of full data set Correction of full data set |

Trial information

Trial identification

| | |
|-----------------------|-------------|
| Sponsor protocol code | I8F-MC-GPIF |
|-----------------------|-------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT05412004 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Eli Lilly and Company |
| Sponsor organisation address | Lilly Corporate Center, Indianapolis, IN, United States, 46285 |
| Public contact | Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877-CTLilly, |
| Scientific contact | Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877-285-4559, |

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

| | |
|--|---------------|
| Analysis stage | Final |
| Date of interim/final analysis | 29 March 2024 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 29 March 2024 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that QW (once weekly) tirzepatide at the MTD (maximum-tolerated dose) (10 mg or 15 mg) is superior to placebo for mean percent decrease in AHI (Apnea-Hypopnea Index).

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 21 June 2022 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|--------------------|
| Country: Number of subjects enrolled | United States: 149 |
| Country: Number of subjects enrolled | China: 37 |
| Country: Number of subjects enrolled | Japan: 20 |
| Country: Number of subjects enrolled | Taiwan: 16 |
| Country: Number of subjects enrolled | Brazil: 84 |
| Country: Number of subjects enrolled | Mexico: 69 |
| Country: Number of subjects enrolled | Australia: 25 |
| Country: Number of subjects enrolled | Germany: 46 |
| Country: Number of subjects enrolled | Czechia: 23 |
| Worldwide total number of subjects | 469 |
| EEA total number of subjects | 69 |

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) | 418 |
| From 65 to 84 years | 51 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Not applicable

Period 1

| | |
|------------------------------|--------------------------------|
| Period 1 title | Overall study (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Investigator, Subject |

Arms

| | |
|------------------------------|-----|
| Are arms mutually exclusive? | Yes |
|------------------------------|-----|

| | |
|------------------|----------------------|
| Arm title | Tirzepatide MTD_GPI1 |
|------------------|----------------------|

Arm description:

Participants not on positive airway pressure (PAP) therapy received a maximum tolerated dose (MTD) of 10 milligrams (mg) or 15 mg of Tirzepatide once weekly (QW) as a subcutaneous (SC) injection for 52 weeks, including the initial dose escalation by 2.5 mg every 4 weeks.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | Tirzepatide |
| Investigational medicinal product code | LY3298176 |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled pen |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Participants not on PAP therapy received 10 mg or 15 mg Tirzepatide QW after initial titration of 2.5 mg every 4 weeks as SC injection for 52 weeks.

| | |
|------------------|--------------|
| Arm title | Placebo_GPI1 |
|------------------|--------------|

Arm description:

Participants not on PAP therapy received placebo QW as an SC injection for 52 weeks.

| | |
|--|--|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled pen |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Participants not on PAP therapy received placebo QW as SC injection for 52 weeks.

| | |
|------------------|--------------|
| Arm title | TZP MTD_GPI2 |
|------------------|--------------|

Arm description:

Participants who are on PAP therapy received an MTD of 10 mg or 15 mg of Tirzepatide QW as an SC injection for 52 weeks, including the initial dose escalation by 2.5 mg every 4 weeks.

| | |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

| | |
|--|--|
| Investigational medicinal product name | Tirzepatide |
| Investigational medicinal product code | LY3298176 |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled pen |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Participants who are on PAP therapy received 10 mg or 15 mg Tirzepatide QW after initial titration of 2.5 mg every 4 weeks as SC injection for 52 weeks.

| | |
|------------------|--------------|
| Arm title | Placebo_GPI2 |
|------------------|--------------|

Arm description:

Participants who are on PAP therapy received placebo QW as SC injection for 52 weeks.

| | |
|--|--|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled pen |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Participants who are on PAP therapy received placebo QW as SC injection for 52 weeks.

| Number of subjects in period 1 | Tirzepatide MTD_GPI1 | Placebo_GPI1 | TZP MTD_GPI2 |
|--|-------------------------|--------------|--------------|
| Started | 114 | 120 | 120 |
| Received at Least One Dose of Study Drug | 114 | 120 | 119 |
| Completed | 101 | 86 | 113 |
| Not completed | 13 | 34 | 7 |
| Consent withdrawn by subject | 4 | 19 | 4 |
| Physician decision | - | 1 | - |
| Participant quit treatment due to their schedule | - | - | - |
| Screen Failure | - | - | - |
| Adverse event, non-fatal | - | 2 | 1 |
| Patient could not assist to site | - | 1 | - |
| Pregnancy | - | 1 | - |
| Protocol Violation | 1 | - | - |
| Lost to follow-up | 3 | - | - |
| Assigned Treatment by Mistake | 5 | 10 | 2 |

| Number of subjects in period 1 | Placebo_GPI2 |
|--|--------------|
| Started | 115 |
| Received at Least One Dose of Study Drug | 114 |
| Completed | 89 |
| Not completed | 26 |
| Consent withdrawn by subject | 14 |

| | |
|--|---|
| Physician decision | - |
| Participant quit treatment due to their schedule | 1 |
| Screen Failure | 1 |
| Adverse event, non-fatal | 5 |
| Patient could not assist to site | - |
| Pregnancy | - |
| Protocol Violation | - |
| Lost to follow-up | - |
| Assigned Treatment by Mistake | 5 |

Baseline characteristics

Reporting groups

| | |
|---|----------------------|
| Reporting group title | Tirzepatide MTD_GPI1 |
| Reporting group description: | |
| Participants not on positive airway pressure (PAP) therapy received a maximum tolerated dose (MTD) of 10 milligrams (mg) or 15 mg of Tirzepatide once weekly (QW) as a subcutaneous (SC) injection for 52 weeks, including the initial dose escalation by 2.5 mg every 4 weeks. | |
| Reporting group title | Placebo_GPI1 |
| Reporting group description: | |
| Participants not on PAP therapy received placebo QW as an SC injection for 52 weeks. | |
| Reporting group title | TZP MTD_GPI2 |
| Reporting group description: | |
| Participants who are on PAP therapy received an MTD of 10 mg or 15 mg of Tirzepatide QW as an SC injection for 52 weeks, including the initial dose escalation by 2.5 mg every 4 weeks. | |
| Reporting group title | Placebo_GPI2 |
| Reporting group description: | |
| Participants who are on PAP therapy received placebo QW as SC injection for 52 weeks. | |

| Reporting group values | Tirzepatide MTD_GPI1 | Placebo_GPI1 | TZP MTD_GPI2 |
|---|----------------------|--------------|--------------|
| Number of subjects | 114 | 120 | 120 |
| Age categorical | | | |
| Units: Subjects | | | |
| <50years | 63 | 62 | 54 |
| >=50years | 51 | 58 | 66 |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 47.3 | 48.4 | 47.3 |
| standard deviation | ± 11.0 | ± 11.9 | ± 11.0 |
| Gender categorical | | | |
| All randomized participants. | | | |
| Units: Subjects | | | |
| Female | 36 | 41 | 33 |
| Male | 78 | 79 | 87 |
| Ethnicity (NIH/OMB) | | | |
| All randomized participants. | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 51 | 47 | 38 |
| Not Hispanic or Latino | 63 | 69 | 82 |
| Unknown or Not Reported | 0 | 4 | 0 |
| Race (NIH/OMB) | | | |
| All randomized participants. | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 9 | 9 | 10 |
| Asian | 23 | 24 | 17 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 6 | 7 | 8 |
| White | 74 | 80 | 85 |
| More than one race | 2 | 0 | 0 |

| | | | |
|---|---------|---------|---------|
| Unknown or Not Reported | 0 | 0 | 0 |
| Region of Enrollment | | | |
| All randomized participants. | | | |
| Units: Subjects | | | |
| United States | 35 | 36 | 41 |
| China | 14 | 14 | 4 |
| Japan | 3 | 4 | 7 |
| Taiwan | 5 | 4 | 4 |
| Brazil | 24 | 25 | 18 |
| Mexico | 20 | 19 | 14 |
| Australia | 1 | 5 | 10 |
| Germany | 7 | 7 | 16 |
| Czechia | 5 | 6 | 6 |
| Baseline apnea-hypopnea index (AHI) | | | |
| AHI is the number of apneas or hypopneas recorded via polysomnography during the study per hour of sleep. Apnea is defined as a cessation of airflow lasting at least 10 seconds, and hypopnea as a decrease in airflow by at least 30% from baseline for at least 10 seconds occurring with a drop in oxygen saturation (SpO ₂) by at least 4%. AHI values are categorized as 5-15 episodes/hr = mild; 15-<30 episodes/hr = moderate; and ≥ 30 episodes/h = severe. A significant reduction in values indicates a positive outcome.0 | | | |
| Units: events per hour | | | |
| arithmetic mean | 52.86 | 50.13 | 46.08 |
| standard deviation | ± 30.50 | ± 31.47 | ± 22.35 |

| | | | |
|---|--------------|-------|--|
| Reporting group values | Placebo_GPI2 | Total | |
| Number of subjects | 115 | 469 | |
| Age categorical | | | |
| Units: Subjects | | | |
| <50years | 45 | 224 | |
| ≥50years | 70 | 245 | |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 48.4 | - | |
| standard deviation | ± 11.9 | - | |
| Gender categorical | | | |
| All randomized participants. | | | |
| Units: Subjects | | | |
| Female | 32 | 142 | |
| Male | 83 | 327 | |
| Ethnicity (NIH/OMB) | | | |
| All randomized participants. | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 38 | 174 | |
| Not Hispanic or Latino | 76 | 290 | |
| Unknown or Not Reported | 1 | 5 | |
| Race (NIH/OMB) | | | |
| All randomized participants. | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 9 | 37 | |
| Asian | 16 | 80 | |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | |
| Black or African American | 3 | 24 | |

| | | | |
|---|---------|-----|--|
| White | 86 | 325 | |
| More than one race | 0 | 2 | |
| Unknown or Not Reported | 1 | 1 | |
| Region of Enrollment | | | |
| All randomized participants. | | | |
| Units: Subjects | | | |
| United States | 37 | 149 | |
| China | 5 | 37 | |
| Japan | 6 | 20 | |
| Taiwan | 3 | 16 | |
| Brazil | 17 | 84 | |
| Mexico | 16 | 69 | |
| Australia | 9 | 25 | |
| Germany | 16 | 46 | |
| Czechia | 6 | 23 | |
| Baseline apnea-hypopnea index (AHI) | | | |
| AHI is the number of apneas or hypopneas recorded via polysomnography during the study per hour of sleep. Apnea is defined as a cessation of airflow lasting at least 10 seconds, and hypopnea as a decrease in airflow by at least 30% from baseline for at least 10 seconds occurring with a drop in oxygen saturation (SpO) by at least 4%. AHI values are categorized as 5-15 episodes/hr = mild; 15-<30 episodes/hr = moderate; and ≥ 30 episodes/h = severe. A significant reduction in values indicates a positive outcome.0 | | | |
| Units: events per hour | | | |
| arithmetic mean | 53.10 | | |
| standard deviation | ± 30.23 | - | |

End points

End points reporting groups

| | |
|---|----------------------|
| Reporting group title | Tirzepatide MTD_GPI1 |
| Reporting group description: Participants not on positive airway pressure (PAP) therapy received a maximum tolerated dose (MTD) of 10 milligrams (mg) or 15 mg of Tirzepatide once weekly (QW) as a subcutaneous (SC) injection for 52 weeks, including the initial dose escalation by 2.5 mg every 4 weeks. | |
| Reporting group title | Placebo_GPI1 |
| Reporting group description: Participants not on PAP therapy received placebo QW as an SC injection for 52 weeks. | |
| Reporting group title | TZP MTD_GPI2 |
| Reporting group description: Participants who are on PAP therapy received an MTD of 10 mg or 15 mg of Tirzepatide QW as an SC injection for 52 weeks, including the initial dose escalation by 2.5 mg every 4 weeks. | |
| Reporting group title | Placebo_GPI2 |
| Reporting group description: Participants who are on PAP therapy received placebo QW as SC injection for 52 weeks. | |

Primary: Change From Baseline in Apnea-Hypopnea Index (AHI)

| | |
|--|--|
| End point title | Change From Baseline in Apnea-Hypopnea Index (AHI) |
| End point description: AHI, Apnea-Hypopnea Index, is the number of apneas or hypopneas recorded via polysomnography during the study per hour of sleep. Apnea is defined as a cessation of airflow lasting at least 10 seconds, and hypopnea as a decrease in airflow by at least 30% from baseline for at least 10 seconds occurring with a drop in oxygen saturation (SpO ₂) by at least 4%. AHI values are categorized as 5-15 events/hr = mild; 15-<30 events/hr = moderate; and ≥ 30 events/hr = severe. A significant reduction in values indicates a positive outcome. Analysis Population Description (APD): Modified intent-to-treat (mITT) population consisting of all randomized participants who are exposed to at least 1 dose of study intervention and have evaluable data for this outcome. | |
| End point type | Primary |
| End point timeframe: Baseline, Week 52 | |

| End point values | Tirzepatide MTD_GPI1 | Placebo_GPI1 | TZP MTD_GPI2 | Placebo_GPI2 |
|-------------------------------------|----------------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 100 | 86 | 110 | 87 |
| Units: events/hour | | | | |
| least squares mean (standard error) | -25.25 (± 2.06) | -5.25 (± 2.11) | -29.27 (± 1.99) | -5.51 (± 2.21) |

Statistical analyses

| | |
|----------------------------|-------------------------------------|
| Statistical analysis title | Statistical Analysis 1 |
| Comparison groups | Tirzepatide MTD_GPI1 v Placebo_GPI1 |

| | |
|---|---------------------------|
| Number of subjects included in analysis | 186 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 ^[1] |
| Method | ANCOVA |
| Parameter estimate | LS Mean Change difference |
| Point estimate | -20.01 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -25.82 |
| upper limit | -14.2 |

Notes:

[1] - ANCOVA model was used with baseline, geographic region, sex, treatment (Type III sum of squares) as covariates.

| | |
|---|-----------------------------|
| Statistical analysis title | Statistical Analysis 2 |
| Comparison groups | TZP MTD_GPI2 v Placebo_GPI2 |
| Number of subjects included in analysis | 197 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 ^[2] |
| Method | ANCOVA |
| Parameter estimate | LS Mean Change difference |
| Point estimate | -23.77 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -29.61 |
| upper limit | -17.93 |

Notes:

[2] - ANCOVA model was used with baseline, geographic region, sex, treatment (Type III sum of squares) as covariates.

Secondary: Percent Change From Baseline in AHI

| | |
|--|-------------------------------------|
| End point title | Percent Change From Baseline in AHI |
| End point description: | |
| Percent Change From Baseline in AHI was evaluated. APD: mITT population consisting of all randomized participants who are exposed to at least 1 dose of study intervention and have evaluable data for this outcome. | |
| End point type | Secondary |
| End point timeframe: | |
| Baseline, Week 52 | |

| End point values | Tirzepatide MTD_GPI1 | Placebo_GPI1 | TZP MTD_GPI2 | Placebo_GPI2 |
|-------------------------------------|-------------------------|---------------------|----------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 100 | 86 | 110 | 87 |
| Units: percentage change | | | | |
| least squares mean (standard error) | -50.68 (\pm 5.90) | -3.03 (\pm 7.07) | -58.72 (\pm 5.28) | -2.50 (\pm 6.95) |

Statistical analyses

| Statistical analysis title | Statistical Analysis 1 |
|---|-------------------------------------|
| Comparison groups | Tirzepatide MTD_GPI1 v Placebo_GPI1 |
| Number of subjects included in analysis | 186 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 ^[3] |
| Method | ANCOVA |
| Parameter estimate | LS Mean Change difference |
| Point estimate | -47.65 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -65.76 |
| upper limit | -29.55 |

Notes:

[3] - ANCOVA model was used with baseline, geographic region, sex, treatment (Type III sum of squares) as covariates.

| Statistical analysis title | Statistical Analysis 2 |
|---|-----------------------------|
| Comparison groups | TZP MTD_GPI2 v Placebo_GPI2 |
| Number of subjects included in analysis | 197 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 ^[4] |
| Method | ANCOVA |
| Parameter estimate | LS Mean Change difference |
| Point estimate | -56.21 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -73.73 |
| upper limit | -38.7 |

Notes:

[4] - ANCOVA model was used with baseline, geographic region, sex, treatment (Type III sum of squares) as covariates.

Secondary: Percentage of Participants With $\geq 50\%$ AHI Reduction From Baseline

| | |
|-----------------|---|
| End point title | Percentage of Participants With $\geq 50\%$ AHI Reduction From Baseline |
|-----------------|---|

End point description:

The percentage of participants achieving $\geq 50\%$ AHI reduction from baseline to Week 52 was evaluated.

APD: mITT population consisting of all randomized participants who are exposed to at least 1 dose of study intervention and have evaluable data for this outcome.

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Week 52 | |

| End point values | Tirzepatide MTD_GPI1 | Placebo_GPI1 | TZP MTD_GPI2 | Placebo_GPI2 |
|-----------------------------------|----------------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 100 | 86 | 110 | 87 |
| Units: Percentage of participants | | | | |
| number (not applicable) | 61.22 | 18.96 | 72.40 | 23.25 |

Statistical analyses

| Statistical analysis title | Statistical Analysis 1 |
|---|-------------------------------------|
| Comparison groups | Tirzepatide MTD_GPI1 v Placebo_GPI1 |
| Number of subjects included in analysis | 186 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Regression, Logistic |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 42.77 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 30.76 |
| upper limit | 54.79 |

| Statistical analysis title | Statistical Analysis 2 |
|---|-----------------------------|
| Comparison groups | TZP MTD_GPI2 v Placebo_GPI2 |
| Number of subjects included in analysis | 197 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Regression, Logistic |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 48.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 36.55 |
| upper limit | 60.65 |

Secondary: Percentage of Participants With AHI <5 or With AHI 5-14 With Epworth Sleepiness Scale (ESS) ≤10

| | |
|-----------------|---|
| End point title | Percentage of Participants With AHI <5 or With AHI 5-14 With Epworth Sleepiness Scale (ESS) ≤10 |
|-----------------|---|

End point description:

The percentage of participants with OSA remission (AHI <5 events per hour of sleep) or with mild OSA without excessive daytime sleepiness (AHI 5-14 events per hour of sleep with ESS ≤10) at Week 52 was evaluated. The ESS is used to assess improvements in excessive daytime sleepiness from baseline to Week 52. The ESS is an 8-item, participant-completed measure that asks the participant to rate, on a scale of 0 (no chance of dozing) to 3 (high chance of dozing), their usual chances of dozing in 8 different daytime situations, with a recall period of "in recent times." The ESS total score is the sum of the 8-item scores and ranges from 0 to 24, with higher scores indicating greater daytime sleepiness.

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Week 52 | |

| End point values | Tirzepatide MTD_GPI1 | Placebo_GPI1 | TZP MTD_GPI2 | Placebo_GPI2 |
|-----------------------------------|----------------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 100 | 86 | 110 | 87 |
| Units: percentage of participants | | | | |
| number (not applicable) | 42.17 | 15.88 | 50.24 | 14.33 |

Statistical analyses

| | |
|---|-------------------------------------|
| Statistical analysis title | Statistical Analysis 1 |
| Comparison groups | Tirzepatide MTD_GPI1 v Placebo_GPI1 |
| Number of subjects included in analysis | 186 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Regression, Logistic |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 28.74 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 18.27 |
| upper limit | 39.22 |

| | |
|----------------------------|-----------------------------|
| Statistical analysis title | Statistical Analysis 2 |
| Comparison groups | TZP MTD_GPI2 v Placebo_GPI2 |

| | |
|---|----------------------|
| Number of subjects included in analysis | 197 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Regression, Logistic |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 33.22 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 22.12 |
| upper limit | 44.31 |

Secondary: Change From Baseline in Sleep Apnea-Specific Hypoxic Burden (SASHB) (% Min/Hour)

| | |
|-----------------|--|
| End point title | Change From Baseline in Sleep Apnea-Specific Hypoxic Burden (SASHB) (% Min/Hour) |
|-----------------|--|

End point description:

SASHB is determined by measuring the respiratory event-associated area under the curve for oxygen desaturation from pre-event baseline and represents the cumulative burden of intermittent hypoxia caused by OSA-related sleep-disordered breathing at sleep. Percent change in SASHB from baseline to Week 52 was evaluated. APD: mITT population consisting of all randomized participants who are exposed to at least 1 dose of study intervention and have evaluable data for this outcome.

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

End point timeframe:

Baseline, Week 52

| End point values | Tirzepatide MTD_GPI1 | Placebo_GPI1 | TZP MTD_GPI2 | Placebo_GPI2 |
|-------------------------------------|----------------------|------------------|-------------------|-------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 100 | 86 | 110 | 87 |
| Units: %.min/hr | | | | |
| least squares mean (standard error) | -95.19 (± 4.081) | -25.07 (± 9.804) | -102.98 (± 3.758) | -41.69 (± 11.313) |

Statistical analyses

| | |
|----------------------------|-------------------------------------|
| Statistical analysis title | Statistical Analysis 1 |
| Comparison groups | Tirzepatide MTD_GPI1 v Placebo_GPI1 |

| | |
|---|----------------------------|
| Number of subjects included in analysis | 186 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Median difference (net) |
| Point estimate | -70.13 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -90.94 |
| upper limit | -49.31 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 10.619 |

| | |
|---|-----------------------------|
| Statistical analysis title | Statistical Analysis 2 |
| Comparison groups | TZP MTD_GPI2 v Placebo_GPI2 |
| Number of subjects included in analysis | 197 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Median difference (net) |
| Point estimate | -61.29 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -84.66 |
| upper limit | -37.93 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 11.921 |

Secondary: Change From Baseline in Patient-Reported Outcomes Measurement Information System (PROMIS) Short Form Sleep-Related Impairment 8a (PROMIS SRI) and PROMIS Short Form Sleep Disturbance 8b (PROMIS SD)

| | |
|-----------------|--|
| End point title | Change From Baseline in Patient-Reported Outcomes Measurement Information System (PROMIS) Short Form Sleep-Related Impairment 8a (PROMIS SRI) and PROMIS Short Form Sleep Disturbance 8b (PROMIS SD) |
|-----------------|--|

End point description:

PROMIS SRI consists of 8 items that assess self-reported perceptions of alertness, sleepiness, and tiredness during usual waking hours and perceived functional impairments associated with sleep problems. PROMIS SRI has a recall period of "in the past 7 days" and each item is rated on a 5-point scale from "not at all" to "very much." PROMIS SD consists of 8 items that assess self-reported perceptions of sleep quality, sleep depth, and restoration associated with sleep. PROMIS SD has a recall period of "in the past 7 days" and each item is rated on a 5-point scale ranging from "not at all" to "very much," "never" to "always," or "very poor" to "very good." For both PROMIS SRI and PROMIS SD, item responses are used to generate T-scores which are standardized scores with a mean of 50 and a standard deviation of 10 (score range cannot be specified for T-scores). Higher T-scores indicate worse outcomes; more sleep-related impairment (PROMIS SRI) or more sleep disturbance (PROMIS SD).

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

End point timeframe:

Baseline, Week 52

APD: mITT population consisting of all randomized participants who are exposed to at least 1 dose of study intervention and have evaluable data for this outcome.

| End point values | Tirzepatide MTD_GPI1 | Placebo_GPI1 | TZP MTD_GPI2 | Placebo_GPI2 |
|-------------------------------------|-------------------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 90 | 79 | 93 | 79 |
| Units: score on a scale | | | | |
| least squares mean (standard error) | | | | |
| Sleep Disturbance | -4.47 (± 0.69) | -2.44 (± 0.70) | -6.98 (± 0.82) | -3.08 (± 0.88) |
| Sleep-Related Impairment | -6.57 (± 0.83) | -3.13 (± 0.80) | -8.18 (± 0.95) | -3.91 (± 1.03) |

Statistical analyses

| Statistical analysis title | Statistical Analysis 1 |
|--|-------------------------------------|
| Statistical analysis description: Sleep Disturbance | |
| Comparison groups | Tirzepatide MTD_GPI1 v Placebo_GPI1 |
| Number of subjects included in analysis | 169 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.037 ^[5] |
| Method | ANCOVA |
| Parameter estimate | LS Mean Change difference |
| Point estimate | -2.03 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -3.95 |
| upper limit | -0.12 |

Notes:

[5] - ANCOVA model was used with baseline, geographic region, sex, treatment (Type III sum of squares) as covariates.

| Statistical analysis title | Statistical Analysis 2 |
|---|-------------------------------------|
| Statistical analysis description: Sleep Related Impairment | |
| Comparison groups | Tirzepatide MTD_GPI1 v Placebo_GPI1 |
| Number of subjects included in analysis | 169 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.003 ^[6] |
| Method | ANCOVA |
| Parameter estimate | LS Mean Change difference |
| Point estimate | -3.43 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -5.69 |
| upper limit | -1.17 |

Notes:

[6] - ANCOVA model was used with baseline, geographic region, sex, treatment (Type III sum of squares) as covariates.

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical Analysis 3 |
|-----------------------------------|------------------------|

Statistical analysis description:

Sleep Disturbance

| | |
|---|-----------------------------|
| Comparison groups | TZP MTD_GPI2 v Placebo_GPI2 |
| Number of subjects included in analysis | 172 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 ^[7] |
| Method | ANCOVA |
| Parameter estimate | LS Mean Change difference |
| Point estimate | -3.9 |

Confidence interval

| | |
|-------------|---------|
| level | 95 % |
| sides | 2-sided |
| lower limit | -6.21 |
| upper limit | -1.58 |

Notes:

[7] - ANCOVA model was used with baseline, geographic region, sex, treatment (Type III sum of squares) as covariates.

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical Analysis 4 |
|-----------------------------------|------------------------|

Statistical analysis description:

Sleep Related Impairment

| | |
|---|-----------------------------|
| Comparison groups | TZP MTD_GPI2 v Placebo_GPI2 |
| Number of subjects included in analysis | 172 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.002 ^[8] |
| Method | ANCOVA |
| Parameter estimate | LS Mean Change difference |
| Point estimate | -4.26 |

Confidence interval

| | |
|-------------|---------|
| level | 95 % |
| sides | 2-sided |
| lower limit | -6.97 |
| upper limit | -1.56 |

Notes:

[8] - ANCOVA model was used with baseline, geographic region, sex, treatment (Type III sum of squares) as covariates.

Secondary: Percent Change From Baseline in Body Weight

| | |
|-----------------|---|
| End point title | Percent Change From Baseline in Body Weight |
|-----------------|---|

End point description:

Percent Change from Baseline in Body Weight is evaluated. APD: mITT population consisting of all randomized participants who are exposed to at least 1 dose of study intervention and have evaluable data for this outcome.

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Baseline, Week 52 | |

| End point values | Tirzepatide MTD_GPI1 | Placebo_GPI1 | TZP MTD_GPI2 | Placebo_GPI2 |
|---|-------------------------|---------------------|----------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 101 | 87 | 113 | 90 |
| Units: Percent change | | | | |
| least squares mean (standard deviation) | -17.65 (\pm 0.69) | -1.56 (\pm 0.68) | -19.62 (\pm 0.71) | -2.34 (\pm 0.74) |

Statistical analyses

| | |
|---|-------------------------------------|
| Statistical analysis title | Statistical Analysis 1 |
| Comparison groups | Placebo_GPI1 v Tirzepatide MTD_GPI1 |
| Number of subjects included in analysis | 188 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 ^[9] |
| Method | ANCOVA |
| Parameter estimate | LS Mean Change difference |
| Point estimate | -16.09 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -17.99 |
| upper limit | -14.19 |

Notes:

[9] - ANCOVA model was used with baseline, geographic region, sex, baseline OSA severity Group, treatment (Type III sum of squares) as covariates.

| | |
|---|-----------------------------|
| Statistical analysis title | Statistical Analysis 2 |
| Comparison groups | TZP MTD_GPI2 v Placebo_GPI2 |
| Number of subjects included in analysis | 203 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 ^[10] |
| Method | ANCOVA |
| Parameter estimate | LS Mean Change difference |
| Point estimate | -17.28 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -19.29 |
| upper limit | -15.28 |

Notes:

[10] - ANCOVA model was used with baseline, geographic region, sex, baseline OSA severity Group, treatment (Type III sum of squares) as covariates.

Secondary: Change From Baseline in High Sensitivity C Reactive Protein (hsCRP) Concentration

| | |
|-----------------|---|
| End point title | Change From Baseline in High Sensitivity C Reactive Protein (hsCRP) Concentration |
|-----------------|---|

End point description:

HsCRP is a marker for inflammation and was measured from blood samples to identify the presence of inflammation, to determine its severity, and to monitor response to treatment. APD: mITT population consisting of all randomized participants who are exposed to at least 1 dose of study intervention and have evaluable data for this outcome.

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

End point timeframe:

Baseline, Week 52

| End point values | Tirzepatide MTD_GPI1 | Placebo_GPI1 | TZP MTD_GPI2 | Placebo_GPI2 |
|-------------------------------------|-------------------------|--------------------|--------------------|--------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 95 | 84 | 102 | 82 |
| Units: mg (milligram)/L (liter) | | | | |
| least squares mean (standard error) | -1.42 (± 0.151) | -0.70 (± 0.203) | -1.37 (± 0.130) | -0.33 (± 0.236) |

Statistical analyses

| | |
|---|-------------------------------------|
| Statistical analysis title | Statistical Analysis 1 |
| Comparison groups | Tirzepatide MTD_GPI1 v Placebo_GPI1 |
| Number of subjects included in analysis | 179 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.752 ^[11] |
| Method | ANCOVA |
| Parameter estimate | LS Mean Change difference |
| Point estimate | -0.71 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.21 |
| upper limit | -0.22 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.253 |

Notes:

[11] - ANCOVA model was used with baseline, geographic region, sex, baseline OSA severity Group, treatment (Type III sum of squares) as covariates.

| | |
|---|-----------------------------|
| Statistical analysis title | Statistical Analysis 2 |
| Comparison groups | TZP MTD_GPI2 v Placebo_GPI2 |
| Number of subjects included in analysis | 184 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.35 ^[12] |
| Method | ANCOVA |
| Parameter estimate | LS Mean Change difference |
| Point estimate | -1.04 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.57 |
| upper limit | -0.51 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.269 |

Notes:

[12] - ANCOVA model was used with baseline, geographic region, sex, baseline OSA severity Group, treatment (Type III sum of squares) as covariates.

Secondary: Change From Baseline in Systolic Blood Pressure (SBP)

| | |
|--|---|
| End point title | Change From Baseline in Systolic Blood Pressure (SBP) |
| End point description: | |
| Change in systolic blood pressure from baseline to Week 48 is evaluated. APD: mITT population consisting of all randomized participants who are exposed to at least 1 dose of study intervention and have evaluable data for this outcome. | |
| End point type | Secondary |
| End point timeframe: | |
| Baseline, Week 48 | |

| End point values | Tirzepatide MTD_GPI1 | Placebo_GPI1 | TZP MTD_GPI2 | Placebo_GPI2 |
|-------------------------------------|----------------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 100 | 89 | 112 | 91 |
| Units: mmHg | | | | |
| least squares mean (standard error) | -9.46 (± 1.02) | -1.84 (± 1.03) | -7.64 (± 1.03) | -3.94 (± 1.18) |

Statistical analyses

| | |
|-----------------------------------|-------------------------------------|
| Statistical analysis title | Statistical Analysis 1 |
| Comparison groups | Tirzepatide MTD_GPI1 v Placebo_GPI1 |

| | |
|---|---------------------------|
| Number of subjects included in analysis | 189 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 ^[13] |
| Method | ANCOVA |
| Parameter estimate | LS Mean Change difference |
| Point estimate | -7.62 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -10.48 |
| upper limit | -4.77 |

Notes:

[13] - ANCOVA model was used with baseline, geographic region, sex, treatment (Type III sum of squares) as covariates.

| | |
|---|-----------------------------|
| Statistical analysis title | Statistical Analysis 2 |
| Comparison groups | TZP MTD_GPI2 v Placebo_GPI2 |
| Number of subjects included in analysis | 203 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.017 ^[14] |
| Method | ANCOVA |
| Parameter estimate | LS Mean Change difference |
| Point estimate | -3.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -6.75 |
| upper limit | -0.65 |

Notes:

[14] - ANCOVA model was used with baseline, geographic region, sex, treatment (Type III sum of squares) as covariates.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All randomized participants are exposed to at least 1 dose of study intervention. Gender-specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.

Adverse event reporting additional description:

As per the prespecified statistical analysis plan, adverse events were analyzed as per the treatment regimen.

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

Dictionary used

| | |
|--------------------|--------|
| Dictionary name | MedDRA |
| Dictionary version | 26.1 |

Reporting groups

| | |
|-----------------------|----------------------|
| Reporting group title | Tirzepatide MTD_GPI1 |
|-----------------------|----------------------|

Reporting group description:

Participants not on PAP therapy received an MTD of 10 mg or 15 mg of Tirzepatide QW as an SC injection for 52 weeks, including the initial dose escalation by 2.5 mg every 4 weeks.

| | |
|-----------------------|--------------|
| Reporting group title | Placebo_GPI2 |
|-----------------------|--------------|

Reporting group description:

Participants who are on PAP therapy received placebo QW as an SC injection for 52 weeks.

| | |
|-----------------------|--------------|
| Reporting group title | Placebo_GPI1 |
|-----------------------|--------------|

Reporting group description:

Participants not on PAP therapy received placebo QW as an SC injection for 52 weeks.

| | |
|-----------------------|----------------------|
| Reporting group title | Tirzepatide MTD_GPI2 |
|-----------------------|----------------------|

Reporting group description:

Participants who are on PAP therapy received an MTD of 10 mg or 15 mg of Tirzepatide QW as an SC injection for 52 weeks, including the initial dose escalation by 2.5 mg every 4 weeks.

| Serious adverse events | Tirzepatide MTD_GPI1 | Placebo_GPI2 | Placebo_GPI1 |
|---|----------------------|-------------------|-----------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 9 / 114 (7.89%) | 12 / 114 (10.53%) | 7 / 120 (5.83%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| clear cell renal cell carcinoma | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastric cancer | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (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 |
| malignant melanoma | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (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 |
| plasma cell myeloma | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (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 |
| prostate cancer metastatic | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed ^[1] | 0 / 78 (0.00%) | 1 / 82 (1.22%) | 0 / 79 (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 |
| tonsil cancer metastatic | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| aortic stenosis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (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 |
| hypotension | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Surgical and medical procedures | | | |
| nephrectomy | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| chest pain | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| abnormal uterine bleeding | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed ^[2] | 0 / 36 (0.00%) | 1 / 32 (3.13%) | 0 / 41 (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 | | | |
| asthmatic crisis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (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 |
| Psychiatric disorders | | | |
| depression | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (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 |

| | | | |
|--|-----------------|-----------------|-----------------|
| mood swings | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| suicide attempt | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 2 / 114 (1.75%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| road traffic accident | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| tendon injury | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (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 |
| upper limb fracture | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| acute myocardial infarction | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (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 |
| atrial fibrillation | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 2 / 120 (1.67%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| coronary artery disease | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (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 | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| coma | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| presyncope | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (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 | | | |
| diarrhoea | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pancreatitis acute | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| cholelithiasis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 1 / 120 (0.83%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gallbladder polyp | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| acute kidney injury | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hydronephrosis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| nephrolithiasis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| arthritis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (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 |
| intervertebral disc protrusion alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (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 |
| loose body in joint alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| osteoarthritis alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (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 |
| spinal osteoarthritis alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| appendicitis alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (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 |
| dengue fever alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (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 |
| gastroenteritis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pneumonia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (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 |
| Metabolism and nutrition disorders | | | |
| hypokalaemia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| 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 | Tirzepatide MTD_GPI2 | | |
|---|-------------------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 7 / 119 (5.88%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| clear cell renal cell carcinoma | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| gastric cancer | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| malignant melanoma | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| plasma cell myeloma | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| prostate cancer metastatic | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed ^[1] | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| tonsil cancer metastatic | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vascular disorders | | | |
| aortic stenosis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| hypotension | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|--|-----------------|--|--|
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Surgical and medical procedures | | | |
| nephrectomy | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| General disorders and administration site conditions | | | |
| chest pain | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Reproductive system and breast disorders | | | |
| abnormal uterine bleeding | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed ^[2] | 0 / 32 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| asthmatic crisis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Psychiatric disorders | | | |
| depression | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | | |
|--|-----------------------------------|--|--|--|
| mood swings alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 119 (0.00%) 0 / 0 0 / 0 | | | |
| suicide attempt alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 119 (0.00%) 0 / 0 0 / 0 | | | |
| Injury, poisoning and procedural complications road traffic accident alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 119 (0.84%) 0 / 1 0 / 0 | | | |
| tendon injury alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 119 (0.00%) 0 / 0 0 / 0 | | | |
| upper limb fracture alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 119 (0.00%) 0 / 0 0 / 0 | | | |
| Cardiac disorders acute myocardial infarction alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 119 (0.00%) 0 / 0 0 / 0 | | | |
| atrial fibrillation | | | | |

| | | | |
|--|-----------------|--|--|
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| coronary artery disease | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Nervous system disorders | | | |
| cerebral haemorrhage | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| coma | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| presyncope | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal disorders | | | |
| diarrhoea | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| pancreatitis acute | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hepatobiliary disorders | | | |
| cholelithiasis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| gallbladder polyp | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal and urinary disorders | | | |
| acute kidney injury | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| hydronephrosis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| nephrolithiasis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Musculoskeletal and connective tissue disorders | | | |
| arthritis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| intervertebral disc protrusion alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| loose body in joint alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| osteoarthritis alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| spinal osteoarthritis alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| appendicitis alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| dengue fever alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| gastroenteritis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| pneumonia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Metabolism and nutrition disorders | | | |
| hypokalaemia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: Gender-specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: Gender-specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.

Frequency threshold for reporting non-serious adverse events: 0 %

| Non-serious adverse events | Tirzepatide MTD_GPI1 | Placebo_GPI2 | Placebo_GPI1 |
|---|-------------------------|-------------------|-------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 91 / 114 (79.82%) | 82 / 114 (71.93%) | 91 / 120 (75.83%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| adrenal adenoma | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|--|----------------------|----------------------|----------------------|
| benign neoplasm of skin alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| colorectal adenoma alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| enchondromatosis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| metastasis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| melanocytic naevus alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| neoplasm skin alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| seborrhoeic keratosis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 2 | 0 / 120 (0.00%) 0 |
| squamous cell carcinoma of skin alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 1 / 120 (0.83%) 1 |
| Vascular disorders | | | |

| | | | |
|---|----------------------|----------------------|----------------------|
| aortic occlusion alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 1 / 120 (0.83%) 1 |
| haematoma alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| hypertension alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 114 (0.88%) 1 | 2 / 114 (1.75%) 2 | 8 / 120 (6.67%) 9 |
| hypotension alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 3 / 114 (2.63%) 3 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| internal haemorrhage alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| Surgical and medical procedures cochlea implant alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| fascia release alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| intraocular lens implant alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| phlebectomy alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| tooth extraction | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 2 / 114 (1.75%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 3 | 0 | 1 |
| ureteral stent insertion | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| General disorders and administration site conditions | | | |
| administration site reaction | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| application site pruritus | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| application site reaction | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 2 / 114 (1.75%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| asthenia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| chest discomfort | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| chest pain | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| discomfort | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| fatigue | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 2 / 114 (1.75%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| feeling cold | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| influenza like illness | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 1 | 1 |
| injection site bruising | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 3 / 114 (2.63%) | 1 / 120 (0.83%) |
| occurrences (all) | 1 | 3 | 1 |
| injection site erythema | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| injection site pain | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| injection site pruritus | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| injection site rash | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| injection site reaction | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 8 / 114 (7.02%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 70 | 0 | 2 |
| injection site urticaria | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| local reaction | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| malaise | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| oedema peripheral | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 2 / 114 (1.75%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 3 | 1 |
| pain | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| peripheral swelling | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 2 / 120 (1.67%) |
| occurrences (all) | 0 | 0 | 3 |
| pyrexia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 2 / 114 (1.75%) 2 | 1 / 114 (0.88%) 1 | 2 / 120 (1.67%) 2 |
| temperature intolerance alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| thirst alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| Immune system disorders anaphylactic reaction alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 114 (0.88%) 1 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| drug hypersensitivity alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| seasonal allergy alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 114 (0.88%) 4 | 0 / 114 (0.00%) 0 | 2 / 120 (1.67%) 2 |
| Reproductive system and breast disorders benign prostatic hyperplasia alternative dictionary used: MedDRA 26.1 subjects affected / exposed ^[3] occurrences (all) | 0 / 78 (0.00%) 0 | 1 / 82 (1.22%) 1 | 0 / 79 (0.00%) 0 |
| cervical cyst alternative dictionary used: MedDRA 26.1 subjects affected / exposed ^[4] occurrences (all) | 1 / 36 (2.78%) 1 | 0 / 32 (0.00%) 0 | 0 / 41 (0.00%) 0 |
| cervical polyp alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed ^[5] occurrences (all) | 0 / 36 (0.00%) 0 | 0 / 32 (0.00%) 0 | 0 / 41 (0.00%) 0 |
| prostatitis alternative dictionary used: MedDRA 26.1 subjects affected / exposed ^[6] occurrences (all) | 1 / 78 (1.28%) 1 | 1 / 82 (1.22%) 1 | 0 / 79 (0.00%) 0 |
| vaginal haemorrhage alternative dictionary used: MedDRA 26.1 subjects affected / exposed ^[7] occurrences (all) | 0 / 36 (0.00%) 0 | 0 / 32 (0.00%) 0 | 1 / 41 (2.44%) 1 |
| Respiratory, thoracic and mediastinal disorders asthma alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 3 / 120 (2.50%) 3 |
| cough alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 4 / 114 (3.51%) 4 | 2 / 114 (1.75%) 2 | 2 / 120 (1.67%) 3 |
| diaphragmatic disorder alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 114 (0.88%) 1 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| epistaxis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 1 / 120 (0.83%) 1 |
| nasal congestion alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 2 / 114 (1.75%) 2 | 0 / 120 (0.00%) 0 |
| oropharyngeal pain alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| paranasal cyst | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| pleurisy | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| productive cough | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| respiratory disorder | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| pulmonary mass | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| rhinorrhoea | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| rhinitis allergic | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| sinus congestion | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|--|----------------------|----------------------|----------------------|
| snoring alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 114 (0.88%) 1 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| tonsillar inflammation alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 1 / 120 (0.83%) 1 |
| vasomotor rhinitis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| wheezing alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 1 / 120 (0.83%) 1 |
| Psychiatric disorders anxiety disorder alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| anxiety alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 2 / 114 (1.75%) 2 | 2 / 114 (1.75%) 2 | 4 / 120 (3.33%) 4 |
| bruxism alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| confusional state alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 1 / 120 (0.83%) 3 |
| depression alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 3 / 114 (2.63%) | 2 / 114 (1.75%) | 1 / 120 (0.83%) |
| occurrences (all) | 3 | 2 | 1 |
| hallucination | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| insomnia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 3 / 114 (2.63%) | 0 / 114 (0.00%) | 2 / 120 (1.67%) |
| occurrences (all) | 4 | 0 | 2 |
| libido decreased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| mood altered | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| panic attack | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| rapid eye movement sleep behaviour disorder | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| sleep disorder | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Product issues | | | |
| device physical property issue | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Investigations | | | |
| alanine aminotransferase increased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| albumin urine present | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 2 / 114 (1.75%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| amylase increased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| blood creatine phosphokinase increased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 4 / 114 (3.51%) | 3 / 120 (2.50%) |
| occurrences (all) | 1 | 5 | 3 |
| blood bicarbonate increased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| blood calcitonin increased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| blood cholesterol increased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 2 / 120 (1.67%) |
| occurrences (all) | 0 | 0 | 2 |
| blood alkaline phosphatase increased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| blood pressure decreased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| blood osmolarity decreased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| blood glucose increased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 2 | 1 |
| blood creatinine increased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| blood pressure increased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 2 / 114 (1.75%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 2 | 1 |
| blood urea increased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| blood testosterone decreased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| blood pressure measurement | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| cardiac murmur | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| coronavirus test positive | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 1 | 0 | 1 |
| creatinine urine increased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| electrocardiogram t wave inversion | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| gamma-glutamyltransferase increased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| heart rate increased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 5 / 114 (4.39%) | 0 / 114 (0.00%) | 2 / 120 (1.67%) |
| occurrences (all) | 5 | 0 | 2 |
| lipids abnormal | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| lipase increased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 3 / 114 (2.63%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| mean cell volume increased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| occult blood positive | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pancreatic enzymes increased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| protein urine present | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| sars-cov-2 test positive | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 2 / 114 (1.75%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| transaminases increased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| weight decreased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| vitamin d decreased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| white blood cell count decreased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|----------------------|----------------------|----------------------|
| weight increased alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 2 / 120 (1.67%) 2 |
| Injury, poisoning and procedural complications | | | |
| animal bite alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 1 / 120 (0.83%) 1 |
| bone contusion alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| breast injury alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 1 / 120 (0.83%) 1 |
| contusion alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 3 / 114 (2.63%) 3 | 0 / 120 (0.00%) 0 |
| epicondylitis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| eye contusion alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| fall alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 114 (0.88%) 1 | 3 / 114 (2.63%) 5 | 1 / 120 (0.83%) 1 |
| foot fracture alternative dictionary used: | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| head injury | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 2 / 120 (1.67%) |
| occurrences (all) | 0 | 0 | 2 |
| hand fracture | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| iatrogenic injury | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| injection related reaction | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| joint injury | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 1 | 1 |
| lower limb fracture | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| limb injury | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 2 / 114 (1.75%) | 1 / 120 (0.83%) |
| occurrences (all) | 1 | 3 | 1 |
| ligament sprain | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 3 / 114 (2.63%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 3 | 0 | 1 |
| meniscus injury | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| muscle strain | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 1 | 1 |
| muscle rupture | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| nail avulsion | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| overdose | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 4 / 114 (3.51%) | 2 / 114 (1.75%) | 2 / 120 (1.67%) |
| occurrences (all) | 4 | 2 | 2 |
| road traffic accident | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| skin laceration | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| soft tissue injury | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|----------------------|----------------------|----------------------|
| spinal column injury alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 114 (0.88%) 1 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| viiiith nerve injury alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| wrist fracture alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 2 / 114 (1.75%) 2 | 0 / 120 (0.00%) 0 |
| Cardiac disorders angina pectoris alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 2 / 114 (1.75%) 2 | 0 / 120 (0.00%) 0 |
| aortic valve incompetence alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| arrhythmia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| atrioventricular block second degree alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 1 / 120 (0.83%) 1 |
| atrial fibrillation alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 1 / 120 (0.83%) 1 |
| bradycardia alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| bundle branch block right | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| coronary artery disease | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| extrasystoles | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| mitral valve incompetence | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| sinus arrhythmia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| supraventricular extrasystoles | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| supraventricular tachycardia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| tachycardia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 2 / 114 (1.75%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 2 | 0 | 1 |

| | | | |
|--|----------------------|----------------------|----------------------|
| ventricular extrasystoles alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 114 (0.88%) 1 | 0 / 114 (0.00%) 0 | 1 / 120 (0.83%) 1 |
| Nervous system disorders | | | |
| carotid arteriosclerosis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 114 (0.88%) 1 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| carpal tunnel syndrome alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 2 | 0 / 120 (0.00%) 0 |
| dizziness alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 2 / 114 (1.75%) 4 | 3 / 114 (2.63%) 5 | 2 / 120 (1.67%) 2 |
| dysgeusia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 114 (0.88%) 1 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| headache alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 4 / 114 (3.51%) 4 | 1 / 114 (0.88%) 1 | 3 / 120 (2.50%) 6 |
| hypoesthesia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| hypotonia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 1 / 120 (0.83%) 1 |
| lethargy alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 2 / 120 (1.67%) |
| occurrences (all) | 0 | 1 | 2 |
| memory impairment | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| migraine | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 2 / 120 (1.67%) |
| occurrences (all) | 0 | 3 | 2 |
| neuralgia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ophthalmic migraine | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| presyncope | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| sciatica | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 2 / 120 (1.67%) |
| occurrences (all) | 0 | 1 | 2 |
| somnolence | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| syncope | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|----------------------|----------------------|----------------------|
| taste disorder alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 1 / 120 (0.83%) 1 |
| tremor alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 1 / 120 (0.83%) 1 |
| Blood and lymphatic system disorders | | | |
| anaemia macrocytic alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| anaemia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 114 (0.88%) 1 | 2 / 114 (1.75%) 2 | 0 / 120 (0.00%) 0 |
| leukopenia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| macrocytosis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| lymphadenitis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 1 / 120 (0.83%) 1 |
| microcytic anaemia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| neutropenia alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| Ear and labyrinth disorders | | | |
| ear pain | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| sudden hearing loss | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 1 / 120 (0.83%) 1 |
| tinnitus | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| vertigo | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed occurrences (all) | 1 / 114 (0.88%) 1 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| Eye disorders | | | |
| dry eye | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed occurrences (all) | 1 / 114 (0.88%) 1 | 0 / 114 (0.00%) 0 | 1 / 120 (0.83%) 1 |
| photopsia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| vitreous haemorrhage | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed occurrences (all) | 1 / 114 (0.88%) 1 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| vitreous degeneration | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| Gastrointestinal disorders | | | |
| abdominal distension | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 5 / 114 (4.39%) | 2 / 114 (1.75%) | 1 / 120 (0.83%) |
| occurrences (all) | 10 | 2 | 1 |
| abdominal discomfort | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 2 / 114 (1.75%) | 2 / 114 (1.75%) | 1 / 120 (0.83%) |
| occurrences (all) | 3 | 2 | 1 |
| abdominal pain upper | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 4 / 114 (3.51%) | 2 / 114 (1.75%) | 2 / 120 (1.67%) |
| occurrences (all) | 4 | 2 | 6 |
| abdominal pain | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 7 / 114 (6.14%) | 2 / 114 (1.75%) | 4 / 120 (3.33%) |
| occurrences (all) | 7 | 2 | 4 |
| aphthous ulcer | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| barrett's oesophagus | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| colon dysplasia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| constipation | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-------------------|------------------|-------------------|
| subjects affected / exposed | 18 / 114 (15.79%) | 5 / 114 (4.39%) | 3 / 120 (2.50%) |
| occurrences (all) | 25 | 7 | 4 |
| diarrhoea | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 30 / 114 (26.32%) | 10 / 114 (8.77%) | 15 / 120 (12.50%) |
| occurrences (all) | 69 | 15 | 21 |
| diverticulum intestinal | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| dyspepsia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 5 / 114 (4.39%) | 1 / 114 (0.88%) | 2 / 120 (1.67%) |
| occurrences (all) | 5 | 1 | 4 |
| epigastric discomfort | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| enterocolitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| enteritis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| eructation | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 9 / 114 (7.89%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 11 | 1 | 0 |
| erosive oesophagitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| flatulence | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 3 / 114 (2.63%) | 1 / 114 (0.88%) | 1 / 120 (0.83%) |
| occurrences (all) | 4 | 1 | 1 |
| frequent bowel movements | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 1 | 1 |
| gastric polyps | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| gastritis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 2 / 114 (1.75%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| gastrointestinal hypermotility | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 2 |
| gastrooesophageal reflux disease | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 9 / 114 (7.89%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 13 | 0 | 1 |
| haemorrhoids | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 2 / 114 (1.75%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| hiatus hernia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| inguinal hernia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-------------------|-----------------|-------------------|
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| large intestine polyp | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| malocclusion | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| mouth ulceration | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| nausea | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 29 / 114 (25.44%) | 6 / 114 (5.26%) | 12 / 120 (10.00%) |
| occurrences (all) | 59 | 7 | 15 |
| oesophagitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| pancreatitis acute | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pelvic floor dysfunction | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| salivary gland cyst | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|-------------------------|----------------------|----------------------|
| toothache alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 2 / 114 (1.75%) 2 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| vomiting alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 20 / 114 (17.54%) 34 | 1 / 114 (0.88%) 1 | 5 / 120 (4.17%) 6 |
| Hepatobiliary disorders cholelithiasis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| gallbladder polyp alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 114 (0.88%) 1 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| hepatic function abnormal alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| hepatic steatosis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 114 (0.88%) 1 | 2 / 114 (1.75%) 2 | 1 / 120 (0.83%) 1 |
| Skin and subcutaneous tissue disorders actinic keratosis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| acne alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 114 (0.88%) 1 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| alopecia | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 5 / 114 (4.39%) | 1 / 114 (0.88%) | 1 / 120 (0.83%) |
| occurrences (all) | 5 | 1 | 1 |
| angioedema | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| dermatitis allergic | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 1 | 0 | 1 |
| dermal cyst | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| erythema | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| hand dermatitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| night sweats | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| pigmentation disorder | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pruritus | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| psoriasis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| rash pruritic | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| sebaceous hyperplasia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| seborrhoeic dermatitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| skin lesion | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| urticaria | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 2 / 114 (1.75%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Renal and urinary disorders | | | |
| diabetic nephropathy | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| glomerulonephropathy | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 114 (0.88%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| haematuria | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| hydronephrosis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| hypertonic bladder | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| microalbuminuria | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| nephrolithiasis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 3 / 114 (2.63%) | 0 / 114 (0.00%) | 2 / 120 (1.67%) |
| occurrences (all) | 3 | 0 | 2 |
| nephropathy | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| pollakiuria | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| proteinuria | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|----------------------|----------------------|----------------------|
| renal colic alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 1 / 120 (0.83%) 1 |
| urethral stenosis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| urinary incontinence alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| urinary retention alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| Endocrine disorders autoimmune thyroid disorder alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 1 / 120 (0.83%) 1 |
| goitre alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 1 / 120 (0.83%) 1 |
| hyperparathyroidism alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| thyroid mass alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 1 / 120 (0.83%) 1 |
| Musculoskeletal and connective tissue disorders | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| arthritis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| arthralgia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 3 / 114 (2.63%) | 5 / 114 (4.39%) | 6 / 120 (5.00%) |
| occurrences (all) | 3 | 5 | 6 |
| back pain | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 5 / 114 (4.39%) | 2 / 120 (1.67%) |
| occurrences (all) | 1 | 5 | 2 |
| bursitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| extremity contracture | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| intervertebral disc protrusion | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| joint swelling | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| muscle contracture | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| muscle spasms | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| musculoskeletal stiffness | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| musculoskeletal pain | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| musculoskeletal chest pain | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| muscle tightness | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 1 | 1 |
| myalgia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 2 / 114 (1.75%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| myositis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| neck pain | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 1 | 0 | 1 |
| osteoarthritis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 2 / 114 (1.75%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 3 | 1 |

| | | | |
|---|-----------------|-----------------|-----------------|
| pain in extremity | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 2 / 114 (1.75%) | 1 / 114 (0.88%) | 1 / 120 (0.83%) |
| occurrences (all) | 2 | 1 | 1 |
| plantar fasciitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 3 / 120 (2.50%) |
| occurrences (all) | 0 | 0 | 6 |
| sacroiliac joint dysfunction | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| rotator cuff syndrome | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| spinal osteoarthritis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 2 / 114 (1.75%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| spinal pain | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| tendon disorder | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| tendonitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 1 / 114 (0.88%) | 1 / 120 (0.83%) |
| occurrences (all) | 1 | 1 | 2 |
| trigger finger | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|------------------|------------------|
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| torticollis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| vertebral foraminal stenosis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Infections and infestations | | | |
| acute sinusitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 2 / 114 (1.75%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| bronchitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 7 / 114 (6.14%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 7 | 0 |
| covid-19 | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 6 / 114 (5.26%) | 11 / 114 (9.65%) | 10 / 120 (8.33%) |
| occurrences (all) | 6 | 12 | 11 |
| conjunctivitis viral | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| conjunctivitis bacterial | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| conjunctivitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 1 | 1 |
| cystitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 2 / 120 (1.67%) |
| occurrences (all) | 0 | 0 | 2 |
| dengue fever | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| diverticulitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ear infection | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| erysipelas | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| epstein-barr virus infection | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| fungal infection | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| fungal foot infection | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|----------------------|----------------------|----------------------|
| fungal skin infection alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| gastroenteritis viral alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| gastroenteritis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 3 / 114 (2.63%) 3 | 1 / 114 (0.88%) 1 | 4 / 120 (3.33%) 4 |
| gastrointestinal infection alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 2 / 114 (1.75%) 2 | 0 / 120 (0.00%) 0 |
| helicobacter infection alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 114 (0.88%) 1 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| herpes zoster alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 114 (0.88%) 1 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| hordeolum alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 2 / 120 (1.67%) 2 |
| herpes virus infection alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| influenza alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|-------------------|-----------------|
| subjects affected / exposed | 4 / 114 (3.51%) | 3 / 114 (2.63%) | 8 / 120 (6.67%) |
| occurrences (all) | 5 | 3 | 8 |
| lower respiratory tract infection | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 1 | 0 | 1 |
| nasopharyngitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 3 / 114 (2.63%) | 12 / 114 (10.53%) | 8 / 120 (6.67%) |
| occurrences (all) | 3 | 17 | 8 |
| onychomycosis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| oral candidiasis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| otitis externa | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| otitis media acute | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| parasitic gastroenteritis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| paronychia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| pharyngitis streptococcal | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| pneumonia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 2 / 114 (1.75%) | 1 / 114 (0.88%) | 2 / 120 (1.67%) |
| occurrences (all) | 2 | 1 | 2 |
| post procedural infection | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| postoperative wound infection | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 0 | 1 |
| pseudomembranous colitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| respiratory tract infection | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 3 / 114 (2.63%) | 0 / 114 (0.00%) | 1 / 120 (0.83%) |
| occurrences (all) | 3 | 0 | 1 |
| pyelonephritis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| respiratory tract infection viral | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| rhinitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|-----------------|------------------|
| subjects affected / exposed | 0 / 114 (0.00%) | 2 / 114 (1.75%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| sinusitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 2 / 114 (1.75%) | 5 / 114 (4.39%) | 2 / 120 (1.67%) |
| occurrences (all) | 2 | 5 | 2 |
| tonsillitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 2 / 114 (1.75%) | 0 / 120 (0.00%) |
| occurrences (all) | 2 | 2 | 0 |
| tinea pedis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tooth abscess | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| tooth infection | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| upper respiratory tract infection | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 7 / 114 (6.14%) | 8 / 114 (7.02%) | 10 / 120 (8.33%) |
| occurrences (all) | 10 | 9 | 11 |
| urinary tract infection | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 2 / 114 (1.75%) | 1 / 114 (0.88%) | 2 / 120 (1.67%) |
| occurrences (all) | 2 | 1 | 2 |
| viral infection | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|--|----------------------|----------------------|----------------------|
| viral upper respiratory tract infection alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 1 / 120 (0.83%) 1 |
| Metabolism and nutrition disorders dehydration alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| decreased appetite alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 4 / 114 (3.51%) 4 | 3 / 114 (2.63%) 3 | 0 / 120 (0.00%) 0 |
| diabetes mellitus alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
| dyslipidaemia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 114 (0.88%) 1 | 2 / 114 (1.75%) 2 | 3 / 120 (2.50%) 3 |
| gout alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 2 / 114 (1.75%) 6 | 0 / 114 (0.00%) 0 | 0 / 120 (0.00%) 0 |
| glucose tolerance impaired alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 2 / 120 (1.67%) 2 |
| hypertriglyceridaemia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 114 (0.00%) 0 | 1 / 114 (0.88%) 1 | 2 / 120 (1.67%) 2 |
| hyperuricaemia alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 2 / 114 (1.75%) | 4 / 114 (3.51%) | 4 / 120 (3.33%) |
| occurrences (all) | 3 | 5 | 4 |
| hyperglycaemia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 1 / 120 (0.83%) |
| occurrences (all) | 0 | 1 | 1 |
| hyperkalaemia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 2 / 114 (1.75%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| hyperlipidaemia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 2 / 120 (1.67%) |
| occurrences (all) | 1 | 0 | 2 |
| hypoglycaemia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| hyponatraemia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| increased appetite | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 114 (0.88%) | 0 / 114 (0.00%) | 0 / 120 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| iron deficiency | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 1 / 114 (0.88%) | 0 / 120 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| type 2 diabetes mellitus | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 114 (0.00%) | 3 / 114 (2.63%) | 2 / 120 (1.67%) |
| occurrences (all) | 0 | 3 | 2 |

| | | | |
|---|--------------------------|--------------------------|--------------------------|
| vitamin d deficiency alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 114 (0.88%) 1 | 1 / 114 (0.88%) 1 | 0 / 120 (0.00%) 0 |
|---|--------------------------|--------------------------|--------------------------|

| Non-serious adverse events | Tirzepatide MTD_GPI2 | | |
|--|--------------------------|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 98 / 119 (82.35%) | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| adrenal adenoma alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| benign neoplasm of skin alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| colorectal adenoma alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| enchondromatosis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| metastasis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| melanocytic naevus alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| neoplasm skin alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|--|--|--|
| <p>subjects affected / exposed</p> <p>0 / 119 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | | |
| <p>seborrhoeic keratosis</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>0 / 119 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | | |
| <p>squamous cell carcinoma of skin</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>0 / 119 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | | |
| <p>Vascular disorders</p> <p>aortic occlusion</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>0 / 119 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>haematoma</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>0 / 119 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>hypertension</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>2 / 119 (1.68%)</p> <p>occurrences (all)</p> <p>2</p> <p>hypotension</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>0 / 119 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>internal haemorrhage</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>0 / 119 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | | |
| <p>Surgical and medical procedures</p> <p>cochlea implant</p> <p>alternative dictionary used: MedDRA 26.1</p> | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| fascia release | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| intraocular lens implant | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| phlebectomy | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| tooth extraction | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| ureteral stent insertion | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| General disorders and administration site conditions | | | |
| administration site reaction | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| application site pruritus | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| application site reaction | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| asthenia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 2 | | |
| chest discomfort | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| chest pain | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| discomfort | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| fatigue | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 4 / 119 (3.36%) | | |
| occurrences (all) | 22 | | |
| feeling cold | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 2 | | |
| influenza like illness | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| injection site bruising | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 2 / 119 (1.68%) | | |
| occurrences (all) | 2 | | |

| | | | |
|---|-----------------|--|--|
| injection site erythema | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 2 / 119 (1.68%) | | |
| occurrences (all) | 13 | | |
| injection site pain | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| injection site pruritus | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 2 / 119 (1.68%) | | |
| occurrences (all) | 13 | | |
| injection site rash | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| injection site reaction | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 6 / 119 (5.04%) | | |
| occurrences (all) | 44 | | |
| injection site urticaria | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| local reaction | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 8 | | |
| malaise | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| oedema peripheral | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|--|--|--|
| <p>subjects affected / exposed</p> <p>0 / 119 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | | |
| <p>pain</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>2 / 119 (1.68%)</p> <p>occurrences (all)</p> <p>2</p> | | | |
| <p>peripheral swelling</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>0 / 119 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | | |
| <p>pyrexia</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>0 / 119 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | | |
| <p>temperature intolerance</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>2 / 119 (1.68%)</p> <p>occurrences (all)</p> <p>2</p> | | | |
| <p>thirst</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>0 / 119 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | | |
| <p>Immune system disorders</p> <p>anaphylactic reaction</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>0 / 119 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | | |
| <p>drug hypersensitivity</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>1 / 119 (0.84%)</p> <p>occurrences (all)</p> <p>1</p> | | | |
| <p>seasonal allergy</p> <p>alternative dictionary used: MedDRA 26.1</p> | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| Reproductive system and breast disorders | | | |
| benign prostatic hyperplasia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed ^[3] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| cervical cyst | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed ^[4] | 0 / 32 (0.00%) | | |
| occurrences (all) | 0 | | |
| cervical polyp | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed ^[5] | 1 / 32 (3.13%) | | |
| occurrences (all) | 1 | | |
| prostatitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed ^[6] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| vaginal haemorrhage | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed ^[7] | 0 / 32 (0.00%) | | |
| occurrences (all) | 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| asthma | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| cough | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 3 / 119 (2.52%) | | |
| occurrences (all) | 3 | | |
| diaphragmatic disorder | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| epistaxis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| nasal congestion | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 4 / 119 (3.36%) | | |
| occurrences (all) | 4 | | |
| oropharyngeal pain | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| paranasal cyst | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| pleurisy | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| productive cough | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| respiratory disorder | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| pulmonary mass | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |

| | | | |
|---|---------------------------------|--|--|
| <p>rhinorrhoea</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 119 (0.00%)</p> <p>0</p> | | |
| <p>rhinitis allergic</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 119 (0.00%)</p> <p>0</p> | | |
| <p>sinus congestion</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 119 (0.00%)</p> <p>0</p> | | |
| <p>snoring</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 119 (0.00%)</p> <p>0</p> | | |
| <p>tonsillar inflammation</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 119 (0.00%)</p> <p>0</p> | | |
| <p>vasomotor rhinitis</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 119 (0.00%)</p> <p>0</p> | | |
| <p>wheezing</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 119 (0.00%)</p> <p>0</p> | | |
| <p>Psychiatric disorders</p> <p>anxiety disorder</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>anxiety</p> <p>alternative dictionary used: MedDRA 26.1</p> | <p>0 / 119 (0.00%)</p> <p>0</p> | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| bruxism | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| confusional state | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| depression | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| hallucination | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| insomnia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 2 / 119 (1.68%) | | |
| occurrences (all) | 2 | | |
| libido decreased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| mood altered | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| panic attack | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|--|---|--|--|
| <p>rapid eye movement sleep behaviour disorder</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 119 (0.00%)</p> <p>0</p> | | |
| <p>sleep disorder</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 119 (0.00%)</p> <p>0</p> | | |
| <p>Product issues</p> <p>device physical property issue</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 119 (0.00%)</p> <p>0</p> | | |
| <p>Investigations</p> <p>alanine aminotransferase increased</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>albumin urine present</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>amylase increased</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>blood creatine phosphokinase increased</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>blood bicarbonate increased</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 119 (0.00%)</p> <p>0</p> <p>0 / 119 (0.00%)</p> <p>0</p> <p>1 / 119 (0.84%)</p> <p>2</p> <p>1 / 119 (0.84%)</p> <p>1</p> <p>0 / 119 (0.00%)</p> <p>0</p> | | |

| | | | |
|---|----------------------|--|--|
| blood calcitonin increased alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 119 (0.84%) 1 | | |
| blood cholesterol increased alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| blood alkaline phosphatase increased alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| blood pressure decreased alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| blood osmolarity decreased alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 119 (0.84%) 1 | | |
| blood glucose increased alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| blood creatinine increased alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| blood pressure increased alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 119 (0.84%) 1 | | |
| blood urea increased alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| blood testosterone decreased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| blood pressure measurement | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| cardiac murmur | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| coronavirus test positive | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| creatinine urine increased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| electrocardiogram t wave inversion | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| gamma-glutamyltransferase increased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| heart rate increased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 2 | | |

| | | | |
|---|-----------------|--|--|
| lipids abnormal | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| lipase increased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 4 / 119 (3.36%) | | |
| occurrences (all) | 5 | | |
| mean cell volume increased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| occult blood positive | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| pancreatic enzymes increased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| protein urine present | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| sars-cov-2 test positive | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| transaminases increased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| weight decreased | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|--|--|--|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>1 / 119 (0.84%)</p> <p>1</p> | | | |
| <p>vitamin d decreased</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>0 / 119 (0.00%)</p> <p>0</p> | | | |
| <p>white blood cell count decreased</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>1 / 119 (0.84%)</p> <p>1</p> | | | |
| <p>weight increased</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>0 / 119 (0.00%)</p> <p>0</p> | | | |
| <p>Injury, poisoning and procedural complications</p> <p>animal bite</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>0 / 119 (0.00%)</p> <p>0</p> <p>bone contusion</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>1 / 119 (0.84%)</p> <p>1</p> <p>breast injury</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>0 / 119 (0.00%)</p> <p>0</p> <p>contusion</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>1 / 119 (0.84%)</p> <p>1</p> <p>epicondylitis</p> <p>alternative dictionary used: MedDRA 26.1</p> | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| eye contusion | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| fall | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| foot fracture | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| head injury | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| hand fracture | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| iatrogenic injury | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| injection related reaction | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| joint injury | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|---|-----------------|--|--|
| lower limb fracture | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| limb injury | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| ligament sprain | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| meniscus injury | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| muscle strain | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| muscle rupture | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| nail avulsion | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| overdose | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 2 | | |
| road traffic accident | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| skin laceration | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 2 / 119 (1.68%) | | |
| occurrences (all) | 2 | | |
| soft tissue injury | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| spinal column injury | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| viiiith nerve injury | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| wrist fracture | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cardiac disorders | | | |
| angina pectoris | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| aortic valve incompetence | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| arrhythmia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| atrioventricular block second degree | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| atrial fibrillation | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| bradycardia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| bundle branch block right | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| coronary artery disease | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| extrasystoles | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| mitral valve incompetence | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| sinus arrhythmia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|---|----------------------|--|--|
| supraventricular extrasystoles alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 119 (0.84%) 1 | | |
| supraventricular tachycardia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| tachycardia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| ventricular extrasystoles alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| Nervous system disorders carotid arteriosclerosis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| carpal tunnel syndrome alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| dizziness alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 119 (0.84%) 2 | | |
| dysgeusia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 119 (0.84%) 1 | | |
| headache alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| hypoaesthesia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| hypotonia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| lethargy | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| memory impairment | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| migraine | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| neuralgia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| ophthalmic migraine | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| presyncope | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |

| | | | |
|---|----------------------|--|--|
| sciatica alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 119 (0.84%) 1 | | |
| somnolence alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 119 (0.84%) 1 | | |
| syncope alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 119 (0.84%) 1 | | |
| taste disorder alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| tremor alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| Blood and lymphatic system disorders anaemia macrocytic alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 119 (0.84%) 1 | | |
| anaemia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| leukopenia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 119 (0.84%) 1 | | |
| macrocytosis alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|--|--|--|--|
| <p>subjects affected / exposed</p> <p>1 / 119 (0.84%)</p> <p>occurrences (all)</p> <p>1</p> | | | |
| <p>lymphadenitis</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>0 / 119 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | | |
| <p>microcytic anaemia</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>0 / 119 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | | |
| <p>neutropenia</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>0 / 119 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | | |
| <p>Ear and labyrinth disorders</p> <p>ear pain</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>0 / 119 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>sudden hearing loss</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>0 / 119 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>tinnitus</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>0 / 119 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>vertigo</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>1 / 119 (0.84%)</p> <p>occurrences (all)</p> <p>1</p> | | | |
| <p>Eye disorders</p> <p>dry eye</p> <p>alternative dictionary used: MedDRA 26.1</p> | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| photopsia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| vitreous haemorrhage | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| vitreous degeneration | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| Gastrointestinal disorders | | | |
| abdominal distension | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 4 / 119 (3.36%) | | |
| occurrences (all) | 4 | | |
| abdominal discomfort | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| abdominal pain upper | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 7 / 119 (5.88%) | | |
| occurrences (all) | 8 | | |
| abdominal pain | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 5 / 119 (4.20%) | | |
| occurrences (all) | 8 | | |
| aphthous ulcer | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-------------------|--|--|
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| barrett's oesophagus | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| colon dysplasia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| constipation | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 18 / 119 (15.13%) | | |
| occurrences (all) | 19 | | |
| diarrhoea | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 26 / 119 (21.85%) | | |
| occurrences (all) | 56 | | |
| diverticulum intestinal | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| dyspepsia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 11 / 119 (9.24%) | | |
| occurrences (all) | 11 | | |
| epigastric discomfort | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| enterocolitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|---|------------------|--|--|
| enteritis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| eructation | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 10 / 119 (8.40%) | | |
| occurrences (all) | 26 | | |
| erosive oesophagitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| flatulence | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| frequent bowel movements | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| gastric polyps | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| gastritis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 2 / 119 (1.68%) | | |
| occurrences (all) | 2 | | |
| gastrointestinal hypermotility | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| gastrooesophageal reflux disease | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-------------------|--|--|
| subjects affected / exposed | 6 / 119 (5.04%) | | |
| occurrences (all) | 8 | | |
| haemorrhoids | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 2 / 119 (1.68%) | | |
| occurrences (all) | 2 | | |
| hiatus hernia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| inguinal hernia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| large intestine polyp | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| malocclusion | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| mouth ulceration | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| nausea | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 26 / 119 (21.85%) | | |
| occurrences (all) | 58 | | |
| oesophagitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|--|------------------------|--|--|
| pancreatitis acute alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 119 (0.84%) 1 | | |
| pelvic floor dysfunction alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| salivary gland cyst alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 119 (0.84%) 1 | | |
| toothache alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| vomiting alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 11 / 119 (9.24%) 18 | | |
| Hepatobiliary disorders cholelithiasis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 2 / 119 (1.68%) 2 | | |
| gallbladder polyp alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| hepatic function abnormal alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| hepatic steatosis alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 2 / 119 (1.68%) | | |
| occurrences (all) | 2 | | |
| Skin and subcutaneous tissue disorders | | | |
| actinic keratosis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| acne | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| alopecia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 5 / 119 (4.20%) | | |
| occurrences (all) | 5 | | |
| angioedema | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| dermatitis allergic | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| dermal cyst | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| erythema | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| hand dermatitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| night sweats | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| pigmentation disorder | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| pruritus | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| psoriasis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| rash pruritic | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| sebaceous hyperplasia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| seborrhoeic dermatitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| skin lesion | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|---|----------------------|--|--|
| urticaria alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 119 (0.84%) 1 | | |
| Renal and urinary disorders | | | |
| diabetic nephropathy alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| glomerulonephropathy alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| haematuria alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 119 (0.84%) 1 | | |
| hydronephrosis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| hypertonic bladder alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| microalbuminuria alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| nephrolithiasis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 3 / 119 (2.52%) 4 | | |
| nephropathy alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| pollakiuria | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| proteinuria | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| renal colic | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| urethral stenosis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| urinary incontinence | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| urinary retention | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| Endocrine disorders | | | |
| autoimmune thyroid disorder | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| goitre | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|--|--|--|
| <p>subjects affected / exposed</p> <p>0 / 119 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>hyperparathyroidism</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>0 / 119 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>thyroid mass</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>0 / 119 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | | |
| <p>Musculoskeletal and connective tissue disorders</p> <p>arthritis</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>1 / 119 (0.84%)</p> <p>occurrences (all)</p> <p>1</p> <p>arthralgia</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>4 / 119 (3.36%)</p> <p>occurrences (all)</p> <p>4</p> <p>back pain</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>1 / 119 (0.84%)</p> <p>occurrences (all)</p> <p>1</p> <p>bursitis</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>0 / 119 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>extremity contracture</p> <p>alternative dictionary used: MedDRA 26.1</p> <p>subjects affected / exposed</p> <p>0 / 119 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>intervertebral disc protrusion</p> <p>alternative dictionary used: MedDRA 26.1</p> | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| joint swelling | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| muscle contracture | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| muscle spasms | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| musculoskeletal stiffness | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| musculoskeletal pain | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| musculoskeletal chest pain | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| muscle tightness | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| myalgia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|---|-----------------|--|--|
| myositis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| neck pain | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| osteoarthritis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| pain in extremity | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| plantar fasciitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| sacroiliac joint dysfunction | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| rotator cuff syndrome | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| spinal osteoarthritis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| spinal pain | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| tendon disorder | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| tendonitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| trigger finger | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| torticollis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| vertebral foraminal stenosis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| Infections and infestations | | | |
| acute sinusitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| bronchitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 3 / 119 (2.52%) | | |
| occurrences (all) | 3 | | |
| covid-19 | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 8 / 119 (6.72%) | | |
| occurrences (all) | 8 | | |
| conjunctivitis viral | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| conjunctivitis bacterial | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| conjunctivitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 2 / 119 (1.68%) | | |
| occurrences (all) | 2 | | |
| cystitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| dengue fever | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| diverticulitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| ear infection | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| erysipelas | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|------------------------------|-----------------|--|--|
| epstein-barr virus infection | | | |
| alternative dictionary used: | | | |
| MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| | | | |
| fungal infection | | | |
| alternative dictionary used: | | | |
| MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| | | | |
| fungal foot infection | | | |
| alternative dictionary used: | | | |
| MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| | | | |
| fungal skin infection | | | |
| alternative dictionary used: | | | |
| MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| | | | |
| gastroenteritis viral | | | |
| alternative dictionary used: | | | |
| MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| | | | |
| gastroenteritis | | | |
| alternative dictionary used: | | | |
| MedDRA 26.1 | | | |
| subjects affected / exposed | 7 / 119 (5.88%) | | |
| occurrences (all) | 8 | | |
| | | | |
| gastrointestinal infection | | | |
| alternative dictionary used: | | | |
| MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| | | | |
| helicobacter infection | | | |
| alternative dictionary used: | | | |
| MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| | | | |
| herpes zoster | | | |
| alternative dictionary used: | | | |
| MedDRA 26.1 | | | |

| | | | |
|---|-------------------|--|--|
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| hordeolum | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| herpes virus infection | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| influenza | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 3 / 119 (2.52%) | | |
| occurrences (all) | 3 | | |
| lower respiratory tract infection | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| nasopharyngitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 15 / 119 (12.61%) | | |
| occurrences (all) | 24 | | |
| onychomycosis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| oral candidiasis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| otitis externa | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |

| | | | |
|---|-----------------|--|--|
| otitis media acute | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| parasitic gastroenteritis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| paronychia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| pharyngitis streptococcal | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| pneumonia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| post procedural infection | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| postoperative wound infection | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| pseudomembranous colitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| respiratory tract infection | | | |
| alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| pyelonephritis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| respiratory tract infection viral | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| rhinitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| sinusitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 2 / 119 (1.68%) | | |
| occurrences (all) | 2 | | |
| tonsillitis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| tinea pedis | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| tooth abscess | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| tooth infection | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 2 / 119 (1.68%) | | |
| occurrences (all) | 2 | | |

| | | | |
|--|----------------------|--|--|
| upper respiratory tract infection alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 5 / 119 (4.20%) 7 | | |
| urinary tract infection alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| viral infection alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| viral upper respiratory tract infection alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 119 (0.84%) 1 | | |
| Metabolism and nutrition disorders | | | |
| dehydration alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 1 / 119 (0.84%) 1 | | |
| decreased appetite alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 3 / 119 (2.52%) 3 | | |
| diabetes mellitus alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| dyslipidaemia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) | 0 / 119 (0.00%) 0 | | |
| gout alternative dictionary used: MedDRA 26.1 | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| glucose tolerance impaired | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| hypertriglyceridaemia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| hyperuricaemia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| hyperglycaemia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| hyperkalaemia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| hyperlipidaemia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |
| hypoglycaemia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| hyponatraemia | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 1 / 119 (0.84%) | | |
| occurrences (all) | 1 | | |

| | | | |
|---|-----------------|--|--|
| increased appetite | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| iron deficiency | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| type 2 diabetes mellitus | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |
| vitamin d deficiency | | | |
| alternative dictionary used: MedDRA 26.1 | | | |
| subjects affected / exposed | 0 / 119 (0.00%) | | |
| occurrences (all) | 0 | | |

Notes:

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Gender-specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Gender-specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Gender-specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.

[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Gender-specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.

[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Gender-specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-------------------|--|
| 30 September 2022 | Protocol Amendment (b): 1) The secondary objective "Change in AHI." was added. 2) The endpoint for key secondary objective "Change in SBP" has been updated to Week 48 from Week 52. 3) The endpoint for the other secondary objective, "Change in Diastolic Blood Pressure (DBP)," has been updated to Week 48 from Week 52. 4) Changes have been made to the Schedule of Activities to reflect the synchronization of timing of the Columbia-Suicide Severity Rating Scale (C-SSRS) to the Patient Health Questionnaire-9 (PHQ-9). |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported