



Clinical trial results:

Phase 2b multi center, randomised, partial blind parallel cohort study to assess the efficacy and safety of treatment with bepirovirsen in participants with chronic hepatitis B virus (B Clear)

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2020-001083-29 |
| Trial protocol | PL GB BG IT RO |
| Global end of trial date | 18 March 2022 |

Results information

| | |
|--------------------------------|---------------|
| Result version number | v1 |
| This version publication date | 17 March 2023 |
| First version publication date | 17 March 2023 |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | 209668 |
|-----------------------|--------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | GlaxoSmithKline |
| Sponsor organisation address | 980 Great West Road, Brentford, Middlesex, United Kingdom, TW8 9GS |
| Public contact | GlaxoSmithKline, GlaxoSmithKline, 1 8664357343, GSKClinicalSupportHD@gsk.com |
| Scientific contact | GSK Response Center, GlaxoSmithKline, 1 8664357343, GSKClinicalSupportHD@gsk.com |

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

| | |
|--|-------------|
| Analysis stage | Final |
| Date of interim/final analysis | 05 May 2022 |
| Is this the analysis of the primary completion data? | No |

| | |
|----------------------------------|---------------|
| Global end of trial reached? | Yes |
| Global end of trial date | 18 March 2022 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy of the three dosing regimens of bepirovirsen in participants with chronic Hepatitis B Virus (HBV).

Protection of trial subjects:

None.

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 27 July 2020 |
| 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 | Argentina: 12 |
| Country: Number of subjects enrolled | Bulgaria: 24 |
| Country: Number of subjects enrolled | Canada: 30 |
| Country: Number of subjects enrolled | France: 18 |
| Country: Number of subjects enrolled | Germany: 8 |
| Country: Number of subjects enrolled | Hong Kong: 3 |
| Country: Number of subjects enrolled | Italy: 15 |
| Country: Number of subjects enrolled | Japan: 74 |
| Country: Number of subjects enrolled | Korea, Democratic People's Republic of: 46 |
| Country: Number of subjects enrolled | Malaysia: 5 |
| Country: Number of subjects enrolled | Poland: 29 |
| Country: Number of subjects enrolled | Romania: 38 |
| Country: Number of subjects enrolled | Russian Federation: 41 |
| Country: Number of subjects enrolled | Singapore: 37 |
| Country: Number of subjects enrolled | Spain: 14 |
| Country: Number of subjects enrolled | Thailand: 18 |
| Country: Number of subjects enrolled | United Kingdom: 6 |
| Country: Number of subjects enrolled | United States: 11 |
| Country: Number of subjects enrolled | China: 16 |
| Country: Number of subjects enrolled | Philippines: 3 |
| Country: Number of subjects enrolled | South Africa: 6 |
| Country: Number of subjects enrolled | Taiwan: 3 |

| | |
|------------------------------------|-----|
| Worldwide total number of subjects | 457 |
| EEA total number of subjects | 146 |

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) | 432 |
| From 65 to 84 years | 25 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 457 participants were randomized in the study. These 457 participants were from 2 different set of populations (referred here after as on nucleos(t)ide [NA] and not on NA therapy). Participants from these subpopulations were randomized in a ratio of 3:3:3:1 into 4 treatment arms for each population (total of 8 arms).

Period 1

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

Arms

| | |
|------------------------------|--|
| Are arms mutually exclusive? | Yes |
| Arm title | GSK3228836 300mg for 24 weeks (WK) (on NA therapy) |

Arm description:

All participants of this arm received 300 mg GSK3228836 once/week for 24 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11).

| | |
|--|---------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | GSK3228836 and NA therapy |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection/infusion |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

GSK3228836 300mg once a week for 24 weeks, plus a loading dose of GSK3228836 300mg on Day 4 and 11).

| | |
|------------------|--|
| Arm title | GSK3228836 300mg for 12 WK (on NA therapy) |
|------------------|--|

Arm description:

All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by step-down in dose of 150 mg (plus placebo to match to maintain participant blinding) GSK3228836 once/week for 12 weeks.

| | |
|--|---------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | GSK3228836 and NA therapy |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection/infusion |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

GSK3228836 300mg once a week for 12 weeks, plus a loading dose of GSK3228836 300mg on Day 4 and 11). Followed by a step down in dose of 150mg (plus placebo to match to maintain blinding) GSK3228836 once a week for 12 weeks.

| | |
|------------------|--|
| Arm title | GSK3228836 300mg for 12WK + Placebo for 12WK (on NA therapy) |
|------------------|--|

Arm description:

All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by a placebo once/week for 12 weeks.

| | |
|----------|--------------------------|
| Arm type | Experimental and Placebo |
|----------|--------------------------|

| | |
|--|---|
| Investigational medicinal product name | GSK3228836 followed by placebo and NA therapy |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection/infusion |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

All participants of this arm received Placebo once/week for 12 weeks (plus placebo loading doses to match on Day 4 and 11) followed by 300 mg GSK3228836 once/week for 12 weeks.

| | |
|------------------|--|
| Arm title | Placebo for 12WK + GSK3228836 300mg for 12WK (on NA therapy) |
|------------------|--|

Arm description:

All participants of this arm received Placebo once/week for 12 weeks (plus placebo loading doses to match on Day 4 and 11) followed by 300 mg GSK3228836 once/week for 12 weeks

| | |
|--|---|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo followed by GSK3228836 and NA therapy |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection/infusion |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

All participants of this arm received Placebo once/week for 12 weeks (plus placebo loading doses to match on Day 4 and 11) followed by 300 mg GSK3228836 once/week for 12 weeks

| | |
|------------------|--|
| Arm title | GSK3228836 300 mg for 24 weeks (not on NA therapy) |
|------------------|--|

Arm description:

All participants of this arm received 300 mg GSK3228836 once/week for 24 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11).

| | |
|--|---------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | GSK3228836 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection/infusion |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

GSK3228836 300mg once a week for 24 weeks, plus a loading dose of GSK3228836 300mg on Day 4 and 11).

| | |
|------------------|--|
| Arm title | GSK3228836 300 mg for 12 weeks (not on NA therapy) |
|------------------|--|

Arm description:

All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by step-down in dose of 150 mg (plus placebo to match to maintain participant blinding) GSK3228836 once/week for 12 weeks.

| | |
|--|---------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | GSK3228836 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection/infusion |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

GSK3228836 300mg once a week for 12 weeks, plus a loading dose of GSK3228836 300mg on Day 4 and 11). Followed by a step down in dose of 150mg (plus placebo to match to maintain blinding) GSK3228836 once a week for 12 weeks.

| | |
|------------------|--|
| Arm title | GSK3228836 300mg + Placebo for 12WK each (not on NA therapy) |
|------------------|--|

Arm description:

All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by placebo once/week for 12 weeks.

| | |
|--|---------------------------------|
| Arm type | Experimental and Placebo |
| Investigational medicinal product name | GSK3228836 followed by placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection/infusion |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

All participants of this arm received Placebo once/week for 12 weeks (plus placebo loading doses to match on Day 4 and 11) followed by 300 mg GSK3228836 once/week for 12 weeks.

| | |
|------------------|--|
| Arm title | Placebo + GSK3228836 300mg for 12WK each (not on NA therapy) |
|------------------|--|

Arm description:

All participants of this arm received Placebo once/week for 12 weeks (plus placebo loading doses to match on Day 4 and 11) followed by 300 mg GSK3228836 once/week for 12 weeks

| | |
|--|---------------------------------|
| Arm type | Placebo and Experimental |
| Investigational medicinal product name | Placebo followed by GSK3228836 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection/infusion |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

All participants of this arm received Placebo once/week for 12 weeks (plus placebo loading doses to match on Day 4 and 11) followed by 300 mg GSK3228836 once/week for 12 weeks.

| Number of subjects in period 1 | GSK3228836 300mg for 24 weeks (WK) (on NA therapy) | GSK3228836 300mg for 12 WK (on NA therapy) | GSK3228836 300mg for 12WK + Placebo for 12WK (on NA therapy) |
|--------------------------------|--|--|--|
| | | | |
| Started | 68 | 68 | 68 |
| Completed | 65 | 65 | 66 |
| Not completed | 3 | 3 | 2 |
| Consent withdrawn by subject | 3 | - | 1 |
| Physician decision | - | - | - |
| Adverse event, non-fatal | - | 1 | 1 |
| Lost to follow-up | - | 1 | - |
| Protocol deviation | - | 1 | - |

| Number of subjects in period 1 | Placebo for 12WK + GSK3228836 300mg for 12WK (on NA therapy) | GSK3228836 300 mg for 24 weeks (not on NA therapy) | GSK3228836 300 mg for 12 weeks (not on NA therapy) |
|--------------------------------|--|--|--|
| | | | |
| Started | 23 | 70 | 68 |
| Completed | 22 | 64 | 66 |
| Not completed | 1 | 6 | 2 |
| Consent withdrawn by subject | 1 | 5 | 1 |
| Physician decision | - | - | 1 |
| Adverse event, non-fatal | - | 1 | - |
| Lost to follow-up | - | - | - |

| | | | |
|--------------------|---|---|---|
| Protocol deviation | - | - | - |
|--------------------|---|---|---|

| Number of subjects in period 1 | GSK3228836 300mg + Placebo for 12WK each (not on NA therapy) | Placebo + GSK3228836 300mg for 12WK each (not on NA therapy) |
|---------------------------------------|---|---|
| Started | 68 | 24 |
| Completed | 63 | 24 |
| Not completed | 5 | 0 |
| Consent withdrawn by subject | 4 | - |
| Physician decision | - | - |
| Adverse event, non-fatal | 1 | - |
| Lost to follow-up | - | - |
| Protocol deviation | - | - |

Baseline characteristics

Reporting groups

| | |
|---|--|
| Reporting group title | GSK3228836 300mg for 24 weeks (WK) (on NA therapy) |
| Reporting group description: All participants of this arm received 300 mg GSK3228836 once/week for 24 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11). | |
| Reporting group title | GSK3228836 300mg for 12 WK (on NA therapy) |
| Reporting group description: All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by step-down in dose of 150 mg (plus placebo to match to maintain participant blinding) GSK3228836 once/week for 12 weeks. | |
| Reporting group title | GSK3228836 300mg for 12WK + Placebo for 12WK (on NA therapy) |
| Reporting group description: All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by a placebo once/week for 12 weeks. | |
| Reporting group title | Placebo for 12WK + GSK3228836 300mg for 12WK (on NA therapy) |
| Reporting group description: All participants of this arm received Placebo once/week for 12 weeks (plus placebo loading doses to match on Day 4 and 11) followed by 300 mg GSK3228836 once/week for 12 weeks | |
| Reporting group title | GSK3228836 300 mg for 24 weeks (not on NA therapy) |
| Reporting group description: All participants of this arm received 300 mg GSK3228836 once/week for 24 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11). | |
| Reporting group title | GSK3228836 300 mg for 12 weeks (not on NA therapy) |
| Reporting group description: All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by step-down in dose of 150 mg (plus placebo to match to maintain participant blinding) GSK3228836 once/week for 12 weeks. | |
| Reporting group title | GSK3228836 300mg + Placebo for 12WK each (not on NA therapy) |
| Reporting group description: All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by placebo once/week for 12 weeks. | |
| Reporting group title | Placebo + GSK3228836 300mg for 12WK each (not on NA therapy) |
| Reporting group description: All participants of this arm received Placebo once/week for 12 weeks (plus placebo loading doses to match on Day 4 and 11) followed by 300 mg GSK3228836 once/week for 12 weeks | |

| Reporting group values | GSK3228836 300mg for 24 weeks (WK) (on NA therapy) | GSK3228836 300mg for 12 WK (on NA therapy) | GSK3228836 300mg for 12WK + Placebo for 12WK (on NA therapy) |
|------------------------------------|--|--|--|
| Number of subjects | 68 | 68 | 68 |
| Age categorical Units: Subjects | | | |
| From less than 50 years | 37 | 42 | 40 |
| 50 years and over | 31 | 26 | 28 |
| Age continuous Units: years | | | |
| arithmetic mean | 49.0 | 46.1 | 47.4 |
| standard deviation | ± 11.54 | ± 12.60 | ± 11.18 |

| | | | |
|---|----|----|----|
| Sex: Female, Male Units: Participants | | | |
| Female | 20 | 19 | 17 |
| Male | 48 | 49 | 51 |
| Race/Ethnicity, Customized Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 1 |
| Asian | 36 | 35 | 36 |
| Black or African American | 2 | 1 | 4 |
| Mixed Race | 0 | 0 | 1 |
| White | 30 | 32 | 26 |

| Reporting group values | Placebo for 12WK + GSK3228836 300mg for 12WK (on NA therapy) | GSK3228836 300 mg for 24 weeks (not on NA therapy) | GSK3228836 300 mg for 12 weeks (not on NA therapy) |
|---|--|--|--|
| Number of subjects | 23 | 70 | 68 |
| Age categorical Units: Subjects | | | |
| From less than 50 years | 11 | 46 | 49 |
| 50 years and over | 12 | 24 | 19 |
| Age continuous Units: years | | | |
| arithmetic mean | 49.8 | 44.5 | 43.8 |
| standard deviation | ± 11.21 | ± 11.10 | ± 9.92 |
| Sex: Female, Male Units: Participants | | | |
| Female | 6 | 37 | 27 |
| Male | 17 | 33 | 41 |
| Race/Ethnicity, Customized Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 12 | 37 | 44 |
| Black or African American | 0 | 9 | 4 |
| Mixed Race | 0 | 0 | 0 |
| White | 11 | 24 | 20 |

| Reporting group values | GSK3228836 300mg + Placebo for 12WK each (not on NA therapy) | Placebo + GSK3228836 300mg for 12WK each (not on NA therapy) | Total |
|--|--|--|-------|
| Number of subjects | 68 | 24 | 457 |
| Age categorical Units: Subjects | | | |
| From less than 50 years | 54 | 17 | 296 |
| 50 years and over | 14 | 7 | 161 |
| Age continuous Units: years | | | |
| arithmetic mean | 40.7 | 42.4 | - |
| standard deviation | ± 11.10 | ± 12.02 | - |
| Sex: Female, Male Units: Participants | | | |
| Female | 29 | 13 | 168 |
| Male | 39 | 11 | 289 |

| | | | |
|---|----|----|-----|
| Race/Ethnicity, Customized Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 1 |
| Asian | 38 | 12 | 250 |
| Black or African American | 6 | 1 | 27 |
| Mixed Race | 0 | 0 | 1 |
| White | 24 | 11 | 178 |

Subject analysis sets

| | |
|----------------------------|-----------------------------|
| Subject analysis set title | GSK3228836 dose level 300mg |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Represents Pharmacokinetic (PK) set of participants who received GSK3228836 at a dose level of 300 mg once a week. Baseline analysis was not performed for sub group population.

| | |
|----------------------------|-----------------------------|
| Subject analysis set title | GSK3228836 dose level 150mg |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Represents PK set of participants who received GSK3228836 at a dose level of 150 mg once a week. Baseline analysis was not performed for sub group population.

| | |
|----------------------------|-------------------------------|
| Subject analysis set title | Tenofovir disoproxil fumarate |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants who received Tenofovir disoproxil fumarate 245 or 300mg once daily. Baseline analysis was not performed for subgroup population.

| | |
|----------------------------|-----------------------|
| Subject analysis set title | Tenofovir alafenamide |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants who received Tenofovir alafenamide 25 mg once daily or every 2 days. Baseline analysis was not performed for subgroup population.

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

Subject analysis set description:

Participants who received Entecavir 0.5 mg once daily. Baseline analysis was not performed for subgroup population.

| Reporting group values | GSK3228836 dose level 300mg | GSK3228836 dose level 150mg | Tenofovir disoproxil fumarate |
|--|-----------------------------|-----------------------------|-------------------------------|
| Number of subjects | 12 | 12 | 7 |
| Age categorical Units: Subjects | | | |
| From less than 50 years | 0 | 0 | 0 |
| 50 years and over | 0 | 0 | 0 |
| Age continuous Units: years | | | |
| arithmetic mean | | | |
| standard deviation | ± | ± | ± |
| Sex: Female, Male Units: Participants | | | |
| Female | | | |
| Male | | | |

| | | | |
|----------------------------------|---|---|---|
| Race/Ethnicity, Customized | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 0 |
| Mixed Race | 0 | 0 | 0 |
| White | 0 | 0 | 0 |

| Reporting group values | Tenofovir alafenamide | Entecavir | |
|----------------------------------|--------------------------|-----------|--|
| Number of subjects | 5 | 16 | |
| Age categorical | | | |
| Units: Subjects | | | |
| From less than 50 years | 0 | 0 | |
| 50 years and over | 0 | 0 | |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | | | |
| standard deviation | ± | ± | |
| Sex: Female, Male | | | |
| Units: Participants | | | |
| Female | | | |
| Male | | | |
| Race/Ethnicity, Customized | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | |
| Asian | 0 | 0 | |
| Black or African American | 0 | 0 | |
| Mixed Race | 0 | 0 | |
| White | 0 | 0 | |

End points

End points reporting groups

| | |
|---|--|
| Reporting group title | GSK3228836 300mg for 24 weeks (WK) (on NA therapy) |
| Reporting group description: All participants of this arm received 300 mg GSK3228836 once/week for 24 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11). | |
| Reporting group title | GSK3228836 300mg for 12 WK (on NA therapy) |
| Reporting group description: All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by step-down in dose of 150 mg (plus placebo to match to maintain participant blinding) GSK3228836 once/week for 12 weeks. | |
| Reporting group title | GSK3228836 300mg for 12WK + Placebo for 12WK (on NA therapy) |
| Reporting group description: All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by a placebo once/week for 12 weeks. | |
| Reporting group title | Placebo for 12WK + GSK3228836 300mg for 12WK (on NA therapy) |
| Reporting group description: All participants of this arm received Placebo once/week for 12 weeks (plus placebo loading doses to match on Day 4 and 11) followed by 300 mg GSK3228836 once/week for 12 weeks | |
| Reporting group title | GSK3228836 300 mg for 24 weeks (not on NA therapy) |
| Reporting group description: All participants of this arm received 300 mg GSK3228836 once/week for 24 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11). | |
| Reporting group title | GSK3228836 300 mg for 12 weeks (not on NA therapy) |
| Reporting group description: All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by step-down in dose of 150 mg (plus placebo to match to maintain participant blinding) GSK3228836 once/week for 12 weeks. | |
| Reporting group title | GSK3228836 300mg + Placebo for 12WK each (not on NA therapy) |
| Reporting group description: All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by placebo once/week for 12 weeks. | |
| Reporting group title | Placebo + GSK3228836 300mg for 12WK each (not on NA therapy) |
| Reporting group description: All participants of this arm received Placebo once/week for 12 weeks (plus placebo loading doses to match on Day 4 and 11) followed by 300 mg GSK3228836 once/week for 12 weeks | |
| Subject analysis set title | GSK3228836 dose level 300mg |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: Represents Pharmacokinetic (PK) set of participants who received GSK3228836 at a dose level of 300 mg once a week. Baseline analysis was not performed for sub group population. | |
| Subject analysis set title | GSK3228836 dose level 150mg |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: Represents PK set of participants who received GSK3228836 at a dose level of 150 mg once a week. Baseline analysis was not performed for sub group population. | |
| Subject analysis set title | Tenofovir disoproxil fumarate |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: Participants who received Tenofovir disoproxil fumarate 245 or 300mg once daily. Baseline analysis was not performed for subgroup population. | |

| | |
|--|-----------------------|
| Subject analysis set title | Tenofovir alafenamide |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: | |
| Participants who received Tenofovir alafenamide 25 mg once daily or every 2 days. Baseline analysis was not performed for subgroup population. | |
| Subject analysis set title | Entecavir |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: | |
| Participants who received Entecavir 0.5 mg once daily. Baseline analysis was not performed for subgroup population. | |

Primary: Number of participants achieving sustained virologic response (SVR)

| | |
|--|--|
| End point title | Number of participants achieving sustained virologic response (SVR) ^[1] |
| End point description: | |
| The SVR was a composite endpoint defined as Hepatitis B surface antigen (HBsAg) and Hepatitis B virus (HBV) Deoxyribonucleic acid (DNA) levels were less than (<) Lower limit of quantitation (LLOQ) at the planned end of GSK3228836 treatment which is sustained for 24 weeks post-GSK3228836 treatment in the absence of rescue medication. | |
| End point type | Primary |
| End point timeframe: | |
| Up to Week 48 | |

Notes:

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

Justification: No hypothesis was tested using statistical analysis

| End point values | GSK3228836 300mg for 24 weeks (WK) (on NA therapy) | GSK3228836 300mg for 12 WK (on NA therapy) | GSK3228836 300mg for 12WK + Placebo for 12WK (on NA therapy) | Placebo for 12WK + GSK3228836 300mg for 12WK (on NA therapy) |
|-----------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 68 | 67 | 68 | 23 |
| Units: Participants | | | | |
| Number of participants. | 6 | 6 | 2 | 0 |

| End point values | GSK3228836 300 mg for 24 weeks (not on NA therapy) | GSK3228836 300 mg for 12 weeks (not on NA therapy) | GSK3228836 300mg + Placebo for 12WK each (not on NA therapy) | Placebo + GSK3228836 300mg for 12WK each (not on NA therapy) |
|-----------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 70 | 68 | 68 | 24 |
| Units: Participants | | | | |
| Number of participants. | 7 | 4 | 1 | 0 |

Statistical analyses

Secondary: Number of participants with categorical changes from baseline in HBsAg values

| | |
|-----------------|---|
| End point title | Number of participants with categorical changes from baseline in HBsAg values |
|-----------------|---|

End point description:

Participants who achieved a decline in HBsAg values from baseline were reported. Participants were categorized in the following categorical HBsAg decline of <0.5, greater than or equal to (\geq) 0.5, \geq 1, \geq 1.5, and \geq 3 log₁₀ international units per milliliter (IU/mL).

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

End point timeframe:

Baseline and up to Week 24

| End point values | GSK3228836 300mg for 24 weeks (WK) (on NA therapy) | GSK3228836 300mg for 12 WK (on NA therapy) | GSK3228836 300mg for 12WK + Placebo for 12WK (on NA therapy) | Placebo for 12WK + GSK3228836 300mg for 12WK (on NA therapy) |
|--|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 64 | 63 | 63 | 22 |
| Units: Participants | | | | |
| HBsAg decline <0.5 log ₁₀ IU/mL | 12 | 21 | 37 | 4 |
| HBsAg decline \geq 0.5 log ₁₀ IU/mL | 52 | 42 | 20 | 17 |
| HBsAg decline \geq 1 log ₁₀ IU/mL | 48 | 38 | 14 | 17 |
| HBsAg decline \geq 1.5 log ₁₀ IU/mL | 42 | 32 | 12 | 15 |
| HBsAg decline \geq 3 log ₁₀ IU/mL | 34 | 16 | 5 | 10 |

| End point values | GSK3228836 300 mg for 24 weeks (not on NA therapy) | GSK3228836 300 mg for 12 weeks (not on NA therapy) | GSK3228836 300mg + Placebo for 12WK each (not on NA therapy) | Placebo + GSK3228836 300mg for 12WK each (not on NA therapy) |
|--|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 63 | 63 | 58 | 23 |
| Units: Participants | | | | |
| HBsAg decline <0.5 log ₁₀ IU/mL | 8 | 14 | 29 | 8 |
| HBsAg decline \geq 0.5 log ₁₀ IU/mL | 55 | 48 | 22 | 15 |
| HBsAg decline \geq 1 log ₁₀ IU/mL | 51 | 36 | 18 | 15 |
| HBsAg decline \geq 1.5 log ₁₀ IU/mL | 48 | 30 | 9 | 12 |
| HBsAg decline \geq 3 log ₁₀ IU/mL | 35 | 13 | 4 | 9 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants achieving HBsAg and HBV DNA<LLOQ

| | |
|--|---|
| End point title | Number of participants achieving HBsAg and HBV DNA<LLOQ |
| End point description: Participants achieving HBsAg and HBV DNA levels <LLOQ at the end of treatment (EOT) were reported. | |
| End point type | Secondary |
| End point timeframe: Up to Week 24 | |

| End point values | GSK3228836 300mg for 24 weeks (WK) (on NA therapy) | GSK3228836 300mg for 12 WK (on NA therapy) | GSK3228836 300mg for 12WK + Placebo for 12WK (on NA therapy) | Placebo for 12WK + GSK3228836 300mg for 12WK (on NA therapy) |
|-----------------------------|--|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 66 | 66 | 66 | 22 |
| Units: Participants | 16 | 9 | 8 | 4 |

| End point values | GSK3228836 300 mg for 24 weeks (not on NA therapy) | GSK3228836 300 mg for 12 weeks (not on NA therapy) | GSK3228836 300mg + Placebo for 12WK each (not on NA therapy) | Placebo + GSK3228836 300mg for 12WK each (not on NA therapy) |
|-----------------------------|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 67 | 66 | 66 | 24 |
| Units: Participants | 17 | 10 | 6 | 1 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with categorical changes from baseline in HBV DNA values

| | |
|---|---|
| End point title | Number of participants with categorical changes from baseline in HBV DNA values |
| End point description: Participants who achieved a decline in HBV DNA values from baseline were reported. Participants were categorized in the following categorical HBV DNA decline of <1, >=1, >=2, and >=3 log IU/mL. | |
| End point type | Secondary |
| End point timeframe: Baseline and up to Week 24 | |

| End point values | GSK3228836 300mg for 24 weeks (WK) (on NA therapy) | GSK3228836 300mg for 12 WK (on NA therapy) | GSK3228836 300mg for 12WK + Placebo for 12WK (on NA therapy) | Placebo for 12WK + GSK3228836 300mg for 12WK (on NA therapy) |
|--------------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 62 | 60 | 60 | 20 |
| Units: Participants | | | | |
| HBV DNA decline <1 log10 IU/mL | 2 | 0 | 0 | 0 |
| HBV DNA decline ≥1 log10 IU/mL | 11 | 4 | 13 | 3 |
| HBV DNA decline ≥2 log10 IU/mL | 0 | 0 | 0 | 0 |
| HBV DNA decline ≥3 log10 IU/mL | 0 | 0 | 0 | 0 |

| End point values | GSK3228836 300 mg for 24 weeks (not on NA therapy) | GSK3228836 300 mg for 12 weeks (not on NA therapy) | GSK3228836 300mg + Placebo for 12WK each (not on NA therapy) | Placebo + GSK3228836 300mg for 12WK each (not on NA therapy) |
|--------------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 59 | 63 | 58 | 23 |
| Units: Participants | | | | |
| HBV DNA decline <1 log10 IU/mL | 3 | 12 | 21 | 3 |
| HBV DNA decline ≥1 log10 IU/mL | 51 | 44 | 30 | 18 |
| HBV DNA decline ≥2 log10 IU/mL | 40 | 23 | 19 | 14 |
| HBV DNA decline ≥3 log10 IU/mL | 27 | 19 | 11 | 9 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with alanine aminotransferase (ALT) normalization

| | |
|---|--|
| End point title | Number of participants with alanine aminotransferase (ALT) normalization |
| End point description: The ALT normalization (ALT ≤ upper limit of normal [ULN]) over time in absence of rescue medication in participants with baseline ALT > ULN. Participants who achieved ALT normalization were reported. | |
| End point type | Secondary |
| End point timeframe: Baseline and Up to Week 24 | |

| | | | | |
|---|--|--|--|--|
| End point values | GSK3228836 300mg for 24 weeks (WK) (on NA therapy) | GSK3228836 300mg for 12 WK (on NA therapy) | GSK3228836 300mg for 12WK + Placebo for 12WK (on NA therapy) | Placebo for 12WK + GSK3228836 300mg for 12WK (on NA therapy) |
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 6 | 7 | 6 | 2 |
| Units: Participants | | | | |
| Participants with ALT > ULN, At Baseline | 6 | 7 | 6 | 2 |
| Participants with ALT normalization, At Week 24 | 3 | 6 | 5 | 0 |

| | | | | |
|---|--|--|--|--|
| End point values | GSK3228836 300 mg for 24 weeks (not on NA therapy) | GSK3228836 300 mg for 12 weeks (not on NA therapy) | GSK3228836 300mg + Placebo for 12WK each (not on NA therapy) | Placebo + GSK3228836 300mg for 12WK each (not on NA therapy) |
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 20 | 20 | 21 | 9 |
| Units: Participants | | | | |
| Participants with ALT > ULN, At Baseline | 20 | 20 | 21 | 9 |
| Participants with ALT normalization, At Week 24 | 10 | 11 | 8 | 5 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with positive Hepatitis B virus e-antibody (HBeAb)

| | |
|--|---|
| End point title | Number of participants with positive Hepatitis B virus e-antibody (HBeAb) |
| End point description: | |
| Blood samples were collected to assess HBeAb level and participants with positive HBeAb were reported. | |
| End point type | Secondary |
| End point timeframe: | |
| Up to Week 48 | |

| | | | | |
|-----------------------------|--|--|--|--|
| End point values | GSK3228836 300mg for 24 weeks (WK) (on NA therapy) | GSK3228836 300mg for 12 WK (on NA therapy) | GSK3228836 300mg for 12WK + Placebo for 12WK (on NA therapy) | Placebo for 12WK + GSK3228836 300mg for 12WK (on NA therapy) |
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 17 | 19 | 24 | 7 |
| Units: Participants | 3 | 4 | 5 | 2 |

| End point values | GSK3228836 300 mg for 24 weeks (not on NA therapy) | GSK3228836 300 mg for 12 weeks (not on NA therapy) | GSK3228836 300mg + Placebo for 12WK each (not on NA therapy) | Placebo + GSK3228836 300mg for 12WK each (not on NA therapy) |
|-----------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 15 | 15 | 11 | 7 |
| Units: Participants | 6 | 4 | 6 | 3 |

Statistical analyses

No statistical analyses for this end point

Secondary: Median time to ALT normalization

| | |
|-----------------|----------------------------------|
| End point title | Median time to ALT normalization |
|-----------------|----------------------------------|

End point description:

Time to ALT normalization (ALT≤ULN) in the absence of rescue medication in participants with baseline ALT>ULN. Numbers of participants analyzed at Week 24 are as follows for NA therapy population: n=6 in GSK3228836 300mg for 24 WK, n= 7 in GSK3228836 for 12 WK + GSK3228836 150mg for 12 WK, n=6 in GSK3228836 300mg for 12 WK + Placebo for 12 WK, n=2 in Placebo for 12 WK + GSK3228836 300mg for 12 WK, respectively. The numbers of participants analyzed are as follows for the not on NA therapy population: n=20 GSK3228836 300mg for 24 WK, n=20 in GSK3228836 300mg for 12 WK + GSK3228836 150mg for 12 WK, n=21 in GSK3228836 300mg for 12 WK + Placebo for 12 WK, n=9 in Placebo for 12 WK + GSK3228836 300mg for 12 WK arm, respectively.

Note that the upper confidence limit for the GSK3228836 300mg for 24WK (on NA), Placebo for 12WK + GSK3228836 300mg for 12WK (on NA), and GSK3228836 300 mg for 24WK (not on NA) were not estimable but set to 48 weeks (maximum follow up) here.

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

End point timeframe:

Baseline and up to Week 48

| End point values | GSK3228836 300mg for 24 weeks (WK) (on NA therapy) | GSK3228836 300mg for 12 WK (on NA therapy) | GSK3228836 300mg for 12WK + Placebo for 12WK (on NA therapy) | Placebo for 12WK + GSK3228836 300mg for 12WK (on NA therapy) |
|----------------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 6 | 7 | 6 | 2 |
| Units: Weeks | | | | |
| median (confidence interval 95%) | 16.6 (1.1 to 48) | 4.1 (1.0 to 11.9) | 1 (1.0 to 8.1) | 7 (1.1 to 48) |

| End point values | GSK3228836 300 mg for 24 | GSK3228836 300 mg for 12 | GSK3228836 300mg + | Placebo + GSK3228836 |
|------------------|--------------------------|--------------------------|--------------------|----------------------|
|------------------|--------------------------|--------------------------|--------------------|----------------------|

| | weeks (not on NA therapy) | weeks (not on NA therapy) | Placebo for 12WK each (not on NA therapy) | 300mg for 12WK each (not on NA therapy) |
|----------------------------------|------------------------------|------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 20 | 21 | 9 | 24 |
| Units: Weeks | | | | |
| median (confidence interval 95%) | 13.4 (2.1 to 48) | 15.1 (4.3 to 18.1) | 10.7 (5.1 to 21.1) | 18.1 (1 to 32.1) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean HBsAg, HBV DNA, and Hepatitis B virus e antigen (HBeAg) level at indicated time points

| | |
|--|---|
| End point title | Mean HBsAg, HBV DNA, and Hepatitis B virus e antigen (HBeAg) level at indicated time points |
| End point description: | |
| Blood samples were collected from participants to assess HBsAg, HBV DNA, and HBeAg level at indicated time points. | |
| End point type | Secondary |
| End point timeframe: | |
| Up to Week 24 | |

| End point values | GSK3228836 300mg for 24 weeks (WK) (on NA therapy) | GSK3228836 300mg for 12 WK (on NA therapy) | GSK3228836 300mg for 12WK + Placebo for 12WK (on NA therapy) | Placebo for 12WK + GSK3228836 300mg for 12WK (on NA therapy) |
|--------------------------------------|--|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 65 | 65 | 65 | 22 |
| Units: Log10 (IU/mL) | | | | |
| arithmetic mean (standard deviation) | | | | |
| HBsAg, At Week 12 | 1.20 (± 1.878) | 1.04 (± 1.858) | 1.76 (± 1.706) | 3.36 (± 0.431) |
| HBsAg, At Week 24 | 0.65 (± 1.939) | 1.45 (± 1.809) | 2.51 (± 1.536) | 0.83 (± 1.801) |
| HBV DNA, At Week 12 | 0.74 (± 0.654) | 0.86 (± 0.700) | 0.67 (± 0.785) | 0.61 (± 0.682) |
| HBV DNA, At Week 24 | 0.55 (± 0.654) | 0.56 (± 0.649) | 0.56 (± 0.714) | 0.79 (± 0.667) |
| HBeAg, At Week 12 | -0.03 (± 1.074) | -0.34 (± 0.749) | 0.03 (± 1.078) | 0.46 (± 1.460) |
| HBeAg, At Week 24 | -0.041 (± 0.635) | -0.48 (± 0.752) | -0.19 (± 1.071) | 0.08 (± 1.497) |

| End point values | GSK3228836 300 mg for 24 weeks (not on NA therapy) | GSK3228836 300 mg for 12 weeks (not on NA therapy) | GSK3228836 300mg + Placebo for 12WK each (not on NA | Placebo + GSK3228836 300mg for 12WK each (not on NA |
|------------------|---|---|---|---|
|------------------|---|---|---|---|

| | | | therapy) | therapy) |
|--------------------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 64 | 63 | 61 | 24 |
| Units: Log10 (IU/mL) | | | | |
| arithmetic mean (standard deviation) | | | | |
| HBsAg, At Week 12 | 1.39 (± 1.965) | 1.27 (± 2.000) | 1.57 (± 1.808) | 3.68 (± 0.798) |
| HBsAg, At Week 24 | 0.77 (± 2.016) | 1.88 (± 1.915) | 2.88 (± 1.511) | 1.64 (± 2.171) |
| HBV DNA, At Week 12 | 3.00 (± 2.242) | 2.92 (± 2.142) | 2.68 (± 1.996) | 4.96 (± 2.074) |
| HBV DNA, At Week 24 | 2.37 (± 2.137) | 2.93 (± 2.317) | 3.07 (± 1.938) | 3.04 (± 2.224) |
| HBeAg, At Week 12 | 1.53 (± 1.887) | 1.27 (± 1.983) | 0.65 (± 1.715) | 2.70 (± 0.843) |
| HBeAg, At Week 24 | 1.18 (± 2.064) | 1.34 (± 1.936) | 0.89 (± 1.667) | 1.06 (± 2.165) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from Baseline in HBsAg, HBV DNA, and HBeAg level at indicated time points

| | |
|---|---|
| End point title | Mean change from Baseline in HBsAg, HBV DNA, and HBeAg level at indicated time points |
| End point description: | |
| Blood samples were collected from participants to assess HBsAg, HBV DNA, and HBAg level at indicated time points. | |
| End point type | Secondary |
| End point timeframe: | |
| Baseline and up to Week 48 | |

| End point values | GSK3228836 300mg for 24 weeks (WK) (on NA therapy) | GSK3228836 300mg for 12 WK (on NA therapy) | GSK3228836 300mg for 12WK + Placebo for 12WK (on NA therapy) | Placebo for 12WK + GSK3228836 300mg for 12WK (on NA therapy) |
|--------------------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 65 | 65 | 65 | 22 |
| Units: log IU/mL. | | | | |
| arithmetic mean (standard deviation) | | | | |
| HBsAg, Week 12 | -2.09 (± 1.649) | -2.23 (± 1.597) | -1.59 (± 1.474) | -0.03 (± 0.089) |
| HBsAg, Week 24 | -2.62 (± 1.653) | -1.81 (± 1.488) | -0.83 (± 1.248) | -2.57 (± 1.671) |
| HBV DNA, Week 12 | 0.24 (± 0.793) | 0.47 (± 0.773) | 0.16 (± 0.942) | 0.19 (± 0.727) |
| HBV DNA, Week 24 | 0.06 (± 0.831) | 0.17 (± 0.661) | 0.09 (± 0.928) | 0.33 (± 0.928) |
| HBeAg, Week 12 | -0.52 (± 0.874) | -0.42 (± 0.480) | -0.33 (± 0.343) | -0.17 (± 0.453) |
| HBeAg, Week 24 | -0.85 (± 1.071) | -0.56 (± 0.811) | -0.46 (± 0.595) | -0.56 (± 0.598) |

| End point values | GSK3228836 300 mg for 24 weeks (not on NA therapy) | GSK3228836 300 mg for 12 weeks (not on NA therapy) | GSK3228836 300mg + Placebo for 12WK each (not on NA therapy) | Placebo + GSK3228836 300mg for 12WK each (not on NA therapy) |
|--------------------------------------|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 64 | 63 | 61 | 24 |
| Units: log IU/mL. | | | | |
| arithmetic mean (standard deviation) | | | | |
| HBsAg, Week 12 | -2.37 (± 1.585) | -2.41 (± 1.562) | -2.06 (± 1.638) | -0.08 (± 0.292) |
| HBsAg, Week 24 | -2.96 (± 1.656) | -1.77 (± 1.489) | -0.77 (± 1.108) | -2.09 (± 1.764) |
| HBV DNA, Week 12 | -1.96 (± 1.365) | -2.22 (± 1.592) | -1.92 (± 1.349) | -0.54 (± 1.421) |
| HBV DNA, Week 24 | -2.66 (± 1.646) | -2.2 (± 1.68) | -1.52 (± 1.637) | -2.6 (± 2.001) |
| HBeAg, Week 12 | -0.65 (± 0.919) | -1.25 (± 1.522) | -0.94 (± 1.618) | -0.14 (± 0.313) |
| HBeAg, Week 24 | -1.01 (± 1.426) | -1.18 (± 1.532) | -0.70 (± 1.673) | -1.78 (± 2.057) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Hepatitis B virus surface antigen antibody (anti-HBsAg) level

| | |
|-----------------|--|
| End point title | Mean Hepatitis B virus surface antigen antibody (anti-HBsAg) level |
|-----------------|--|

End point description:

Blood samples were collected to assess anti-HBsAg level at indicated timepoints.

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

End point timeframe:

Up to Week 48

| End point values | GSK3228836 300mg for 24 weeks (WK) (on NA therapy) | GSK3228836 300mg for 12 WK (on NA therapy) | GSK3228836 300mg for 12WK + Placebo for 12WK (on NA therapy) | Placebo for 12WK + GSK3228836 300mg for 12WK (on NA therapy) |
|--------------------------------------|--|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 65 | 65 | 66 | 22 |
| Units: Log10 IU/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| At Week 36 | 0.94 (± 0.534) | 0.83 (± 0.401) | 0.74 (± 0.333) | 0.79 (± 0.368) |
| At Week 48 | 0.88 (± 0.471) | 0.77 (± 0.368) | 0.70 (± 0.277) | 0.75 (± 0.326) |

| End point values | GSK3228836 300 mg for 24 weeks (not on NA therapy) | GSK3228836 300 mg for 12 weeks (not on NA therapy) | GSK3228836 300mg + Placebo for 12WK each (not on NA therapy) | Placebo + GSK3228836 300mg for 12WK each (not on NA therapy) |
|--------------------------------------|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 63 | 66 | 63 | 24 |
| Units: Log10 IU/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| At Week 36 | 1.01 (± 0.660) | 0.82 (± 0.385) | 0.74 (± 0.347) | 0.90 (± 0.437) |
| At Week 48 | 0.91 (± 0.567) | 0.79 (± 0.369) | 0.71 (± 0.296) | 0.83 (± 0.356) |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in anti-HBsAg level

| | |
|---|--|
| End point title | Change from Baseline in anti-HBsAg level |
| End point description: | |
| Blood samples were collected to assess anti-HBsAg levels at indicated timepoints. | |
| End point type | Secondary |
| End point timeframe: | |
| Up to Week 48 | |

| End point values | GSK3228836 300mg for 24 weeks (WK) (on NA therapy) | GSK3228836 300mg for 12 WK (on NA therapy) | GSK3228836 300mg for 12WK + Placebo for 12WK (on NA therapy) | Placebo for 12WK + GSK3228836 300mg for 12WK (on NA therapy) |
|--------------------------------------|--|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 65 | 65 | 65 | 22 |
| Units: Log10 IU/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| At Week 36 | 0.28 (± 0.481) | 0.18 (± 0.343) | 0.11 (± 0.319) | 0.13 (± 0.250) |
| At Week 48 | 0.22 (± 0.429) | 0.12 (± 0.335) | 0.07 (± 0.267) | 0.09 (± 0.239) |

| End point values | GSK3228836 300 mg for 24 weeks (not on NA therapy) | GSK3228836 300 mg for 12 weeks (not on NA therapy) | GSK3228836 300mg + Placebo for 12WK each (not on NA therapy) | Placebo + GSK3228836 300mg for 12WK each (not on NA therapy) |
|------------------|---|---|---|---|
|------------------|---|---|---|---|

| | | | | |
|--------------------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 63 | 66 | 62 | 24 |
| Units: Log10 IU/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| At Week 36 | 0.37 (± 0.615) | 0.13 (± 0.353) | 0.12 (± 0.221) | 0.16 (± 0.355) |
| At Week 48 | 0.26 (± 0.507) | 0.10 (± 0.319) | 0.09 (± 0.203) | 0.09 (± 0.203) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean area under the concentration-time curve from time 0 up to 24 hours (AUC0-24h) of GSK3228836

| | |
|------------------------|--|
| End point title | Mean area under the concentration-time curve from time 0 up to 24 hours (AUC0-24h) of GSK3228836 |
| End point description: | Intensive pharmacokinetic (PK) sampling was done in a subset of participants on stable NA therapy to analyze AUC0-24h for GSK3228836. Participants received GSK3228836 weekly. |
| End point type | Secondary |
| End point timeframe: | Up to Week 24 |

| End point values | GSK3228836 dose level 300mg | GSK3228836 dose level 150mg | | |
|---|-----------------------------|-----------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 12 | 12 | | |
| Units: h*ug/mL (hour*micrograms per milliliter) | | | | |
| arithmetic mean (standard deviation) | 140.312 (± 37.3548) | 55.214 (± 22.9901) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean maximum observed concentration (Cmax) of GSK3228836

| | |
|------------------------|---|
| End point title | Mean maximum observed concentration (Cmax) of GSK3228836 |
| End point description: | Intensive PK sampling was done in a subset of participants on stable NA therapy to analyze AUC0-24h for GSK3228836. Participants received GSK3228836 weekly |
| End point type | Secondary |
| End point timeframe: | Up to Week 24 |

| End point values | GSK3228836 dose level 300mg | GSK3228836 dose level 150mg | | |
|--------------------------------------|-----------------------------------|-----------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 12 | 12 | | |
| Units: ug/mL | | | | |
| arithmetic mean (standard deviation) | 14.956 (± 5.6592) | 6.112 (± 2.8112) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Median time of maximum observed concentration (tmax) of GSK3228836

| | |
|--|--|
| End point title | Median time of maximum observed concentration (tmax) of GSK3228836 |
| End point description: Intensive PK sampling was done in a subset of participants on stable NA therapy to analyze AUC0-24h for GSK3228836. Participants received GSK3228836 weekly. | |
| End point type | Secondary |
| End point timeframe: Up to Week 24 | |

| End point values | GSK3228836 dose level 300mg | GSK3228836 dose level 150mg | | |
|-------------------------------|-----------------------------------|-----------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 12 | 12 | | |
| Units: h (hour) | | | | |
| median (full range (min-max)) | 3.017 (2.00 to 5.00) | 3.008 (2.00 to 4.02) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean AUC0-24h of NA therapies

| | |
|---|-------------------------------|
| End point title | Mean AUC0-24h of NA therapies |
| End point description: Intensive PK sampling was done in a subset of participants on stable NA therapy to analyze AUC0-24h. Participants on NA therapy were stratified as per the following NA therapy Tenofovir disoproxil fumarate 245 or 300 mg once daily, Tenofovir alafenamide 25 mg once daily or every 2 days, and Entecavir 0.5 | |

mg once daily.

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Up to week 24 | |

| End point values | Tenofovir disoproxil fumarate | Tenofovir alafenamide | Entecavir | |
|---|-------------------------------|---------------------------|----------------------|--|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | |
| Number of subjects analysed | 5 | 4 | 12 | |
| Units: h*nanograms per milliliter (ng/mL) | | | | |
| arithmetic mean (standard deviation) | 2753.908 (\pm 661.3392) | 308.167 (\pm 104.8297) | 24.43 (\pm 6.761) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Cmax of NA therapies

| | |
|--|---------------------------|
| End point title | Mean Cmax of NA therapies |
| End point description: | |
| Intensive PK sampling was done in a subset of participants on stable NA therapy to analyze Cmax. Participants on NA therapy were stratified as per the following NA therapy Tenofovir disoproxil fumarate 245 or 300 mg once daily, Tenofovir alafenamide 25 mg once a daily or every 2 days, and Entecavir 0.5 mg once daily. | |
| End point type | Secondary |
| End point timeframe: | |
| Up to Week 24 | |

| End point values | Tenofovir disoproxil fumarate | Tenofovir alafenamide | Entecavir | |
|--------------------------------------|-------------------------------|-----------------------|----------------------|--|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | |
| Number of subjects analysed | 7 | 5 | 16 | |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | 318.857 (\pm 95.94) | 19.36 (\pm 5.85) | 6.526 (\pm 2.27) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Ctau of NA therapies

| | |
|--|---------------------------|
| End point title | Mean Ctau of NA therapies |
| End point description: | |
| Intensive PK sampling was done in a subset of participants on stable NA therapy to analyze Ctau. Participants on NA therapy were stratified as per the following NA therapy Tenofovir disoproxil fumarate 245 or 300 mg once daily, Tenofovir alafenamide 25 mg once daily or every 2 days, and Entecavir 0.5 mg once daily. | |
| End point type | Secondary |
| End point timeframe: | |
| Up to Week 24 | |

| End point values | Tenofovir disoproxil fumarate | Tenofovir alafenamide | Entecavir | |
|--------------------------------------|-------------------------------|-----------------------|-----------------------|--|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | |
| Number of subjects analysed | 5 | 4 | 12 | |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | 57.04 (\pm 17.0787) | 10.31 (\pm 3.4802) | 0.478 (\pm 0.1055) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Median tmax of NA therapies

| | |
|--|-----------------------------|
| End point title | Median tmax of NA therapies |
| End point description: | |
| Intensive PK sampling was done in a subset of participants on stable NA therapy to analyze tmax. Participants on NA therapy were stratified as per the following NA therapy Tenofovir disoproxil fumarate 245 or 300 mg once daily, Tenofovir alafenamide 25 mg once a daily or every 2 days, and Entecavir 0.5 mg once daily. | |
| End point type | Secondary |
| End point timeframe: | |
| Up to Week 24 | |

| End point values | Tenofovir disoproxil fumarate | Tenofovir alafenamide | Entecavir | |
|-------------------------------|-------------------------------|-----------------------|----------------------|--|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | |
| Number of subjects analysed | 7 | 5 | 16 | |
| Units: hour | | | | |
| median (full range (min-max)) | 1.000 (0.52 to 1.47) | 1.417 (0.93 to 1.55) | 0.983 (0.48 to 2.02) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Median terminal half-life (t1/2) of GSK3228836

| | |
|-----------------|---|
| End point title | Median terminal half-life (t1/2) of GSK3228836 ^[2] |
|-----------------|---|

End point description:

Blood samples were collected from all participants for t1/2 analysis of GSK3228836. Note: for this endpoint data for more comparable arms GSK3228836 for 24WK and 12 WK from both on NA and not on NA therapy were presented.

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

End point timeframe:

Up to Week 48

Notes:

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

Justification: For Median terminal half-life endpoint only for GSK3228836 300mg 24 weeks and 12 weeks arms were compared. Since both arms are more comparable.

| End point values | GSK3228836 300mg for 24 weeks (WK) (on NA therapy) | GSK3228836 300mg for 12 WK (on NA therapy) | GSK3228836 300 mg for 24 weeks (not on NA therapy) | GSK3228836 300 mg for 12 weeks (not on NA therapy) |
|-------------------------------|--|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 65 | 63 | 62 | 64 |
| Units: Day | | | | |
| median (full range (min-max)) | 28.897 (7.52 to 191.98) | 24.918 (8.84 to 161.83) | 27.846 (10.19 to 149.74) | 38.205 (6.87 to 161.83) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Ctau of GSK3228836

| | |
|-----------------|--|
| End point title | Mean Ctau of GSK3228836 ^[3] |
|-----------------|--|

End point description:

Blood samples were collected from all participants for Ctau analysis of GSK3228836. Note: for this endpoint data for more comparable arms GSK3228836 for 24WK and 12 WK from both on NA and not on NA therapy were presented.

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

End point timeframe:

Up to Week 24

Notes:

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

Justification: For Mean Ctau endpoint only for GSK3228836 300mg 24 weeks and 12 weeks arms were compared. Since both arms are more comparable.

| End point values | GSK3228836 300mg for 24 weeks (WK) (on NA therapy) | GSK3228836 300mg for 12 WK (on NA therapy) | GSK3228836 300 mg for 24 weeks (not on NA therapy) | GSK3228836 300 mg for 12 weeks (not on NA therapy) |
|---|--|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 68 | 68 | 70 | 68 |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 8 n=62, 62, 67, and 65, respectively | 21.009 (± 9.6214) | 47.039 (± 198.1345) | 21.663 (± 14.4479) | 23.46 (± 16.6498) |
| Week 12 n= 66, 64, 63, and, 65, respectively | 23.162 (± 11.8963) | 23.234 (± 11.6993) | 21.777 (± 9.9248) | 22.789 (± 11.7361) |
| Week 24 n=64, 61, 63 and 64, respectively | 31.102 (± 28.7535) | 18.95 (± 14.6513) | 28.158 (± 17.0606) | 20.138 (± 19.023) |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All AEs and SAEs were collected from signing the informed consent until the final follow-up visit at the time point specified in the study.

Adverse event reporting additional description:

The safety population (N=455) included participants who received at least one dose of study treatment. 2 participants from arms GSK3228836 300mg for 12 weeks in both on NA and not on NA therapy population, did not receive study treatment.

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 24.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|-----------------------------|
| Reporting group title | GSK3228836 for 24WK (on NA) |
|-----------------------|-----------------------------|

Reporting group description:

All participants of this arm received 300 mg GSK3228836 once/week for 24 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11).

| | |
|-----------------------|------------------------------|
| Reporting group title | GSK3228836 for 12 WK (on NA) |
|-----------------------|------------------------------|

Reporting group description:

All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by step-down in dose of 150 mg (plus placebo to match to maintain participant blinding) GSK3228836 once/week for 12 weeks.

| | |
|-----------------------|--|
| Reporting group title | GSK3228836+Placebo for 12 WK (on NA therapy) |
|-----------------------|--|

Reporting group description:

All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by placebo once/week for 12 weeks.

| | |
|-----------------------|--|
| Reporting group title | Placebo+GSK3228836 for 12WK each (not on NA) |
|-----------------------|--|

Reporting group description:

All participants of this arm received Placebo once/week for 12 weeks followed by 300 mg GSK3228836 once/week for 12 weeks (plus placebo loading doses to match on Day 4 and 11).

| | |
|-----------------------|---------------------------------|
| Reporting group title | GSK3228836 for 24Wk (not on NA) |
|-----------------------|---------------------------------|

Reporting group description:

All participants of this arm received 300 mg GSK3228836 once/week for 24 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11).

| | |
|-----------------------|---------------------------------|
| Reporting group title | GSK3228836 for 12WK (not on NA) |
|-----------------------|---------------------------------|

Reporting group description:

All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by step-down in dose of 150 mg (plus placebo to match to maintain participant blinding) GSK3228836 once/week for 12 weeks.

| | |
|-----------------------|---|
| Reporting group title | GSK3228836+Placebo for 12WK (not on NA) |
|-----------------------|---|

Reporting group description:

All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by placebo once/week for 12 weeks.

| | |
|-----------------------|--|
| Reporting group title | Placebo+GSK3228836 300mg for 12WK each (on NA) |
|-----------------------|--|

Reporting group description:

All participants of this arm received Placebo once/week for 12 weeks followed by 300 mg GSK3228836 once/week for 12 weeks (plus placebo loading doses to match on Day 4 and 11).

| Serious adverse events | GSK3228836 for 24WK (on NA) | GSK3228836 for 12 WK (on NA) | GSK3228836+Placebo for 12 WK (on NA therapy) |
|---|-----------------------------|------------------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 1 / 67 (1.49%) | 4 / 68 (5.88%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Invasive ductal breast carcinoma | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatocellular carcinoma | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bile duct cancer | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Concussion | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Muscle injury | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (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 column injury | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| Cryoglobulinaemia | | | |

| | | | |
|--|----------------|----------------|----------------|
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (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 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Cerebral infarction | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Chest pain | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Systemic inflammatory response syndrome | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| 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 | | | |
| Cervical dysplasia | | | |

| | | | |
|--|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| 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 | | | |
| Hepatic function abnormal | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Interstitial lung disease | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| COVID-19 pneumonia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis B | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| 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 | Placebo+GSK3228836 for 12WK each (not on NA) | GSK3228836 for 24Wk (not on NA) | GSK3228836 for 12WK (not on NA) |
|--|--|---------------------------------|---------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 6 / 70 (8.57%) | 2 / 67 (2.99%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Invasive ductal breast carcinoma | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatocellular carcinoma | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bile duct cancer | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (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 |
| Injury, poisoning and procedural complications | | | |
| Concussion | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Muscle injury | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spinal column injury | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| 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 | | | |
| Cryoglobulinaemia | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Cerebral infarction | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|----------------|----------------|----------------|
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (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 |
| General disorders and administration site conditions | | | |
| Chest pain | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (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 |
| Systemic inflammatory response syndrome | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (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 | | | |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| Cervical dysplasia | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| 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 | | | |
| Hepatic function abnormal | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (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 | | | |
| Interstitial lung disease | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|----------------|----------------|
| Infections and infestations | | | |
| COVID-19 pneumonia | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis B | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (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 |

| Serious adverse events | GSK3228836+Placebo for 12WK (not on NA) | Placebo+GSK3228836 300mg for 12WK each (on NA) | |
|---|---|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 3 / 68 (4.41%) | 0 / 23 (0.00%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Invasive ductal breast carcinoma | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatocellular carcinoma | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bile duct cancer | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury, poisoning and procedural complications | | | |
| Concussion | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscle injury | | | |

| | | | |
|--|----------------|----------------|--|
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal column injury | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular disorders | | | |
| Cryoglobulinaemia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypotension | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| Cerebral infarction | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General disorders and administration site conditions | | | |
| Chest pain | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Systemic inflammatory response syndrome | | | |

| | | | |
|---|----------------|----------------|--|
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Reproductive system and breast disorders | | | |
| Cervical dysplasia | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Hepatic function abnormal | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Interstitial lung disease | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| COVID-19 pneumonia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis B | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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

| Non-serious adverse events | GSK3228836 for 24WK (on NA) | GSK3228836 for 12 WK (on NA) | GSK3228836+Placebo for 12 WK (on NA therapy) |
|---|-----------------------------|------------------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 56 / 68 (82.35%) | 59 / 67 (88.06%) | 53 / 68 (77.94%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Uterine leiomyoma | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin papilloma | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Leiomyoma | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemangioma of liver | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cervix carcinoma | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neoplasm skin | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hot flush | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypertension | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 1 | 0 | 1 |
| Hypotension | | | |

| | | | |
|--|----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Varicose vein | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vasculitis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular pain | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 5 / 68 (7.35%) | 1 / 67 (1.49%) | 1 / 68 (1.47%) |
| occurrences (all) | 6 | 3 | 1 |
| Chest discomfort | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Feeling abnormal | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 4 / 67 (5.97%) | 1 / 68 (1.47%) |
| occurrences (all) | 1 | 6 | 2 |
| Energy increased | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 5 / 68 (7.35%) | 4 / 67 (5.97%) | 7 / 68 (10.29%) |
| occurrences (all) | 8 | 4 | 13 |
| Chest pain | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site anaesthesia | | | |

| | | | |
|-------------------------------|------------------|------------------|------------------|
| subjects affected / exposed | 1 / 68 (1.47%) | 3 / 67 (4.48%) | 2 / 68 (2.94%) |
| occurrences (all) | 2 | 8 | 4 |
| Injection site bruising | | | |
| subjects affected / exposed | 7 / 68 (10.29%) | 11 / 67 (16.42%) | 7 / 68 (10.29%) |
| occurrences (all) | 36 | 17 | 23 |
| Injection site discolouration | | | |
| subjects affected / exposed | 8 / 68 (11.76%) | 9 / 67 (13.43%) | 14 / 68 (20.59%) |
| occurrences (all) | 22 | 65 | 92 |
| Injection site discomfort | | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 9 / 67 (13.43%) | 9 / 68 (13.24%) |
| occurrences (all) | 13 | 62 | 54 |
| Influenza like illness | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 2 | 0 | 1 |
| Injection site erythema | | | |
| subjects affected / exposed | 36 / 68 (52.94%) | 37 / 67 (55.22%) | 34 / 68 (50.00%) |
| occurrences (all) | 216 | 175 | 194 |
| Injection site haematoma | | | |
| subjects affected / exposed | 5 / 68 (7.35%) | 3 / 67 (4.48%) | 1 / 68 (1.47%) |
| occurrences (all) | 9 | 15 | 3 |
| Injection site haemorrhage | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 2 / 67 (2.99%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Hyperthermia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erosion | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Injection site hypoaesthesia | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Injection site induration | | | |
| subjects affected / exposed | 3 / 68 (4.41%) | 3 / 67 (4.48%) | 4 / 68 (5.88%) |
| occurrences (all) | 14 | 6 | 13 |
| Injection site nodule | | | |

| | | | |
|-----------------------------|------------------|------------------|------------------|
| subjects affected / exposed | 1 / 68 (1.47%) | 2 / 67 (2.99%) | 1 / 68 (1.47%) |
| occurrences (all) | 3 | 2 | 1 |
| Injection site pain | | | |
| subjects affected / exposed | 11 / 68 (16.18%) | 15 / 67 (22.39%) | 21 / 68 (30.88%) |
| occurrences (all) | 45 | 59 | 118 |
| Injection site pruritus | | | |
| subjects affected / exposed | 14 / 68 (20.59%) | 17 / 67 (25.37%) | 15 / 68 (22.06%) |
| occurrences (all) | 88 | 78 | 100 |
| Injection site swelling | | | |
| subjects affected / exposed | 4 / 68 (5.88%) | 4 / 67 (5.97%) | 13 / 68 (19.12%) |
| occurrences (all) | 45 | 12 | 70 |
| Injection site warmth | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 5 / 67 (7.46%) | 2 / 68 (2.94%) |
| occurrences (all) | 2 | 13 | 2 |
| Malaise | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 1 / 67 (1.49%) | 1 / 68 (1.47%) |
| occurrences (all) | 1 | 1 | 1 |
| Nodule | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 1 | 2 |
| Oedema peripheral | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Pain | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 3 / 67 (4.48%) | 2 / 68 (2.94%) |
| occurrences (all) | 1 | 4 | 2 |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vaccination site pain | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Scar inflammation | | | |

| | | | |
|---|------------------|----------------|------------------|
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sensation of foreign body | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Swelling | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 10 / 68 (14.71%) | 6 / 67 (8.96%) | 10 / 68 (14.71%) |
| occurrences (all) | 14 | 8 | 19 |
| Immune system disorders | | | |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Food allergy | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immunodeficiency | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Type III immune complex mediated reaction | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Reproductive system and breast disorders | | | |
| Adenomyosis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysmenorrhoea | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Breast pain | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Cervical polyp | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cervix haemorrhage uterine | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Amenorrhoea | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Menstruation irregular | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Menstrual disorder | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Genital haemorrhage | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Erectile dysfunction | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 2 / 68 (2.94%) |
| occurrences (all) | 0 | 0 | 2 |
| Pelvic pain | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vulvovaginal swelling | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vulvovaginal inflammation | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vaginal discharge | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Catarrh | | | |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cough | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 3 / 67 (4.48%) | 2 / 68 (2.94%) |
| occurrences (all) | 0 | 3 | 2 |
| Dry throat | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal pruritus | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal dryness | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Hyperventilation | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Nasal polyps | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reflux laryngitis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Productive cough | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oropharyngeal pain | | | |

| | | | |
|--------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 2 / 68 (2.94%) | 3 / 67 (4.48%) | 2 / 68 (2.94%) |
| occurrences (all) | 2 | 4 | 3 |
| Oropharyngeal discomfort | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis allergic | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Upper respiratory tract inflammation | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 2 / 67 (2.99%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 3 | 1 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stress | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sleep disorder | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 1 | 1 |
| Irritability | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Insomnia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 2 | 2 |
| Depression | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Depressed mood | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|----------------|
| Investigations | | | |
| Activated partial thromboplastin time prolonged | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 7 / 68 (10.29%) | 8 / 67 (11.94%) | 4 / 68 (5.88%) |
| occurrences (all) | 13 | 10 | 6 |
| Albumin urine present | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Antineutrophil cytoplasmic antibody positive | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 3 / 68 (4.41%) | 1 / 67 (1.49%) | 3 / 68 (4.41%) |
| occurrences (all) | 3 | 1 | 3 |
| Autoantibody positive | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bilirubin conjugated increased | | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Antinuclear antibody positive | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood creatinine increased | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 1 | 0 | 1 |
| Blood creatine increased | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood calcium decreased | | | |

| | | | |
|--------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood potassium increased | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Complement factor C3 decreased | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| C-reactive protein increased | | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 2 | 0 | 1 |
| Body temperature increased | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 7 |
| Blood pressure increased | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Complement factor C4 decreased | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Complement factor abnormal | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Complement factor increased | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Creatinine renal clearance decreased | | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 6 / 67 (8.96%) | 1 / 68 (1.47%) |
| occurrences (all) | 4 | 21 | 2 |
| Glomerular filtration rate decreased | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 1 | 0 | 1 |
| Eosinophil count increased | | | |

| | | | |
|--|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Crystal urine present | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Creatinine urine increased | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| International normalised ratio increased | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immature granulocyte count increased | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatitis B DNA assay positive | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatic enzyme increased | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Liver function test abnormal | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Protein urine present | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Platelet count decreased | | | |
| subjects affected / exposed | 4 / 68 (5.88%) | 0 / 67 (0.00%) | 2 / 68 (2.94%) |
| occurrences (all) | 6 | 0 | 2 |
| Neutrophil count decreased | | | |

| | | | |
|--|----------------|----------------|----------------|
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Mean cell volume decreased | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Total complement activity decreased | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Red blood cells urine positive | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Prothrombin time prolonged | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Transaminases increased | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| White blood cell count decreased | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urine albumin/creatinine ratio | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urine albumin/creatinine ratio increased | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 3 |
| Urine analysis abnormal | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urine leukocyte esterase positive | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary sediment present | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|----------------|----------------|----------------|
| Injury, poisoning and procedural complications | | | |
| Eye injury | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Epicondylitis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Contusion | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Back injury | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Arthropod sting | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Arthropod bite | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Animal bite | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Fall | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Post vaccination syndrome | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Nail injury | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle strain | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Procedural pain | | | |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Injury | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hand fracture | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Foot fracture | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Ligament sprain | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin abrasion | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin injury | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sunburn | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth avulsion | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tooth dislocation | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tooth fracture | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tooth injury | | | |

| | | | |
|--|----------------|----------------|----------------|
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Vaccination complication | | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 2 / 67 (2.99%) | 2 / 68 (2.94%) |
| occurrences (all) | 2 | 3 | 2 |
| Congenital, familial and genetic disorders | | | |
| Dyschromatosis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Cardiac disorders | | | |
| Supraventricular extrasystoles | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Angina pectoris | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Palpitations | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Tachycardia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Ageusia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dizziness | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 2 / 67 (2.99%) | 3 / 68 (4.41%) |
| occurrences (all) | 0 | 2 | 4 |
| Lethargy | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hypoaesthesia | | | |

| | | | |
|--------------------------------------|----------------|----------------|-----------------|
| subjects affected / exposed | 2 / 68 (2.94%) | 2 / 67 (2.99%) | 0 / 68 (0.00%) |
| occurrences (all) | 2 | 6 | 0 |
| Headache | | | |
| subjects affected / exposed | 5 / 68 (7.35%) | 6 / 67 (8.96%) | 8 / 68 (11.76%) |
| occurrences (all) | 10 | 8 | 15 |
| Dysgeusia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Migraine | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 1 | 0 | 1 |
| Somnolence | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Sciatica | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Peripheral sensory neuropathy | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Paraesthesia | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Syncope | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 3 / 67 (4.48%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 4 | 1 |
| Abnormal clotting factor | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Increased tendency to bruise | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Leukocytosis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Leukopenia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymph node pain | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphadenopathy | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 2 / 67 (2.99%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| Eosinophilia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Coagulopathy | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphopenia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Monocytosis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 2 / 67 (2.99%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Polycythaemia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Splenomegaly | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---------------------|---------------------|---------------------|
| Thrombocytosis subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 67 (0.00%) 0 | 0 / 68 (0.00%) 0 |
| Thrombocytopenia subjects affected / exposed occurrences (all) | 4 / 68 (5.88%) 6 | 2 / 67 (2.99%) 2 | 1 / 68 (1.47%) 3 |
| Ear and labyrinth disorders | | | |
| Deafness subjects affected / exposed occurrences (all) | 1 / 68 (1.47%) 1 | 0 / 67 (0.00%) 0 | 0 / 68 (0.00%) 0 |
| Vertigo positional subjects affected / exposed occurrences (all) | 1 / 68 (1.47%) 1 | 0 / 67 (0.00%) 0 | 0 / 68 (0.00%) 0 |
| Ear pain subjects affected / exposed occurrences (all) | 1 / 68 (1.47%) 1 | 0 / 67 (0.00%) 0 | 0 / 68 (0.00%) 0 |
| Meniere's disease subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 67 (0.00%) 0 | 0 / 68 (0.00%) 0 |
| Vertigo subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 67 (0.00%) 0 | 1 / 68 (1.47%) 1 |
| Deafness neurosensory subjects affected / exposed occurrences (all) | 1 / 68 (1.47%) 2 | 0 / 67 (0.00%) 0 | 0 / 68 (0.00%) 0 |
| Eye disorders | | | |
| Asthenopia subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 67 (0.00%) 0 | 0 / 68 (0.00%) 0 |
| Blepharitis subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 67 (0.00%) 0 | 2 / 68 (2.94%) 2 |
| Ocular hyperaemia subjects affected / exposed occurrences (all) | 1 / 68 (1.47%) 1 | 0 / 67 (0.00%) 0 | 0 / 68 (0.00%) 0 |
| Eye pain | | | |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Keratitis | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 1 | 0 | 1 |
| Noninfective conjunctivitis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry eye | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 2 / 68 (2.94%) |
| occurrences (all) | 0 | 0 | 2 |
| Periorbital swelling | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 2 / 67 (2.99%) | 1 / 68 (1.47%) |
| occurrences (all) | 1 | 2 | 1 |
| Abdominal distension | | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 0 / 67 (0.00%) | 2 / 68 (2.94%) |
| occurrences (all) | 3 | 0 | 2 |
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 1 | 0 | 2 |
| Aphthous ulcer | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 2 / 68 (2.94%) |
| occurrences (all) | 0 | 1 | 4 |
| Abdominal tenderness | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Angular cheilitis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| Abdominal pain lower | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 2 / 68 (2.94%) |
| occurrences (all) | 1 | 0 | 2 |
| Change of bowel habit | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Constipation | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 4 / 68 (5.88%) |
| occurrences (all) | 0 | 0 | 4 |
| Dental caries | | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 2 | 0 | 1 |
| Diarrhoea | | | |
| subjects affected / exposed | 6 / 68 (8.82%) | 2 / 67 (2.99%) | 0 / 68 (0.00%) |
| occurrences (all) | 6 | 2 | 0 |
| Faeces discoloured | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry mouth | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Dyspepsia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Faecaloma | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diverticulum intestinal | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Food poisoning | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|----------------------------------|----------------|----------------|----------------|
| Gastritis | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastrointestinal sounds abnormal | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematochezia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival bleeding | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival pain | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gingival ulceration | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Haemorrhoidal haemorrhage | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemorrhoids | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Irritable bowel syndrome | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Large intestine polyp | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Tooth disorder | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| Nausea | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 2 / 68 (2.94%) |
| occurrences (all) | 1 | 0 | 3 |
| Oesophageal spasm | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stomatitis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 2 | 1 |
| Mouth ulceration | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Toothache | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 2 / 68 (2.94%) |
| occurrences (all) | 0 | 0 | 2 |
| Vomiting | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 1 | 0 | 1 |
| Hepatobiliary disorders | | | |
| Gallbladder polyp | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatic cytolysis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatic function abnormal | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hepatic steatosis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertransaminaemia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 2 / 68 (2.94%) |
| occurrences (all) | 0 | 1 | 2 |
| Hepatitis acute | | | |

| | | | |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 67 (0.00%) 0 | 0 / 68 (0.00%) 0 |
| Skin and subcutaneous tissue disorders | | | |
| Alopecia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Acne | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Dermal cyst | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood blister | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Asteatosis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Angioedema | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dry skin | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Dermatitis allergic | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis contact | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Drug reaction with eosinophilia and systemic symptoms | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis | | | |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 1 | 1 |
| Haemorrhage subcutaneous | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 1 / 67 (1.49%) | 2 / 68 (2.94%) |
| occurrences (all) | 1 | 1 | 3 |
| Eczema | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 2 / 68 (2.94%) |
| occurrences (all) | 1 | 0 | 3 |
| Ecchymosis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hand dermatitis | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Papule | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Night sweats | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nail bed bleeding | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 1 | 0 | 1 |
| Petechiae | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 3 / 68 (4.41%) | 2 / 67 (2.99%) | 1 / 68 (1.47%) |
| occurrences (all) | 6 | 2 | 2 |
| Purpura | | | |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 4 / 68 (5.88%) | 1 / 67 (1.49%) | 1 / 68 (1.47%) |
| occurrences (all) | 8 | 7 | 1 |
| Skin discolouration | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 2 / 68 (2.94%) |
| occurrences (all) | 1 | 0 | 3 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash pruritic | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash erythematous | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin hypertrophy | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin plaque | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Umbilical erythema | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 2 / 68 (2.94%) |
| occurrences (all) | 0 | 0 | 2 |
| Urticarial vasculitis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin hyperpigmentation | | | |

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|--|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 67 (0.00%) 0 | 0 / 68 (0.00%) 0 |
| Renal and urinary disorders | | | |
| Cylindruria | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Albuminuria | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Leukocyturia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nephrocalcinosis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nephrolithiasis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nephropathy toxic | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Proteinuria | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 2 / 67 (2.99%) | 2 / 68 (2.94%) |
| occurrences (all) | 3 | 3 | 2 |
| Haematuria | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 2 / 68 (2.94%) |
| occurrences (all) | 0 | 1 | 2 |
| Glycosuria | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysuria | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Ketonuria | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

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| Renal cyst | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urine abnormality | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Endocrine disorders | | | |
| Hyperthyroidism | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hypothyroidism | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Costochondritis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthritis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Back pain | | | |
| subjects affected / exposed | 4 / 68 (5.88%) | 5 / 67 (7.46%) | 6 / 68 (8.82%) |
| occurrences (all) | 5 | 5 | 8 |
| Bone swelling | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Arthralgia | | | |
| subjects affected / exposed | 3 / 68 (4.41%) | 3 / 67 (4.48%) | 6 / 68 (8.82%) |
| occurrences (all) | 5 | 4 | 8 |
| Intervertebral disc protrusion | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Joint swelling | | | |

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| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle spasms | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Muscle twitching | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 5 / 68 (7.35%) | 2 / 67 (2.99%) | 4 / 68 (5.88%) |
| occurrences (all) | 5 | 6 | 4 |
| Flank pain | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 2 / 67 (2.99%) | 2 / 68 (2.94%) |
| occurrences (all) | 1 | 2 | 4 |
| Osteoporosis | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Spinal osteoarthritis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Sjogren's syndrome | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sacral pain | | | |

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| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rotator cuff syndrome | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rheumatoid arthritis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Osteoarthritis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tendonitis | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Infections and infestations | | | |
| Asymptomatic bacteriuria | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bacterial infection | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bacteriuria | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| COVID-19 | | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 8 / 67 (11.94%) | 5 / 68 (7.35%) |
| occurrences (all) | 2 | 8 | 5 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

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| Chronic hepatitis B | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cystitis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhoea infectious | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Epididymitis | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Folliculitis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Genital herpes | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Fungal skin infection | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Furuncle | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Fungal infection | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingivitis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
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| Helicobacter gastritis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hepatitis B | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes dermatitis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Infection | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes virus infection | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hordeolum | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 2 / 68 (2.94%) |
| occurrences (all) | 1 | 0 | 3 |
| Herpes simplex | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site cellulitis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 2 / 67 (2.99%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 1 / 67 (1.49%) | 5 / 68 (7.35%) |
| occurrences (all) | 1 | 1 | 5 |
| Oral herpes | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Oral infection | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
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| Injection site abscess | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis externa | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 1 | 1 |
| Parotitis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periodontitis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Pustule | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
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| Skin infection | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Suspected COVID-19 | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth abscess | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Tooth infection | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Urethritis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 67 (1.49%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |
| Vaginal infection | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vaginitis gardnerella | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 0 / 68 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 67 (0.00%) | 1 / 68 (1.47%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
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| Viral upper respiratory tract infection subjects affected / exposed occurrences (all) | 1 / 68 (1.47%) 1 | 0 / 67 (0.00%) 0 | 0 / 68 (0.00%) 0 |
| Vulvovaginal candidiasis subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 67 (0.00%) 0 | 0 / 68 (0.00%) 0 |
| Metabolism and nutrition disorders | | | |
| Diabetes mellitus subjects affected / exposed occurrences (all) | 1 / 68 (1.47%) 1 | 0 / 67 (0.00%) 0 | 0 / 68 (0.00%) 0 |
| Decreased appetite subjects affected / exposed occurrences (all) | 1 / 68 (1.47%) 1 | 0 / 67 (0.00%) 0 | 0 / 68 (0.00%) 0 |
| Cell death subjects affected / exposed occurrences (all) | 1 / 68 (1.47%) 1 | 0 / 67 (0.00%) 0 | 0 / 68 (0.00%) 0 |
| Hyperglycaemia subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 67 (0.00%) 0 | 0 / 68 (0.00%) 0 |
| Hypokalaemia subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 67 (0.00%) 0 | 0 / 68 (0.00%) 0 |
| Hypoglycaemia subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 67 (0.00%) 0 | 0 / 68 (0.00%) 0 |
| Hypocalcaemia subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 67 (0.00%) 0 | 0 / 68 (0.00%) 0 |
| Hyperkalaemia subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 67 (0.00%) 0 | 0 / 68 (0.00%) 0 |
| Iron deficiency subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 67 (0.00%) 0 | 0 / 68 (0.00%) 0 |
| Polydipsia | | | |

| | | | |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 67 (0.00%) 0 | 0 / 68 (0.00%) 0 |
| Vitamin B complex deficiency subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 67 (0.00%) 0 | 0 / 68 (0.00%) 0 |
| Vitamin D deficiency subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 67 (0.00%) 0 | 0 / 68 (0.00%) 0 |

| Non-serious adverse events | Placebo+GSK3228836 for 12WK each (not on NA) | GSK3228836 for 24Wk (not on NA) | GSK3228836 for 12WK (not on NA) |
|--|--|---------------------------------|---------------------------------|
| Total subjects affected by non-serious adverse events subjects affected / exposed | 19 / 24 (79.17%) | 65 / 70 (92.86%) | 60 / 67 (89.55%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) Uterine leiomyoma subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 1 / 70 (1.43%) 1 | 0 / 67 (0.00%) 0 |
| Skin papilloma subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Leiomyoma subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 1 / 67 (1.49%) 1 |
| Haemangioma of liver subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Cervix carcinoma subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 1 / 70 (1.43%) 1 | 0 / 67 (0.00%) 0 |
| Neoplasm skin subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 1 / 67 (1.49%) 1 |
| Vascular disorders Haematoma subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 1 / 70 (1.43%) 1 | 0 / 67 (0.00%) 0 |
| Hot flush | | | |

| | | | |
|--|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 2 / 70 (2.86%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 2 | 1 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Varicose vein | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vasculitis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vascular pain | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 3 / 70 (4.29%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 3 | 2 |
| Chest discomfort | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Feeling abnormal | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Chills | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 5 / 70 (7.14%) | 2 / 67 (2.99%) |
| occurrences (all) | 0 | 5 | 2 |
| Energy increased | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Fatigue | | | |

| | | | |
|-------------------------------|------------------|------------------|------------------|
| subjects affected / exposed | 0 / 24 (0.00%) | 13 / 70 (18.57%) | 7 / 67 (10.45%) |
| occurrences (all) | 0 | 19 | 15 |
| Chest pain | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Injection site anaesthesia | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 2 | 2 |
| Injection site bruising | | | |
| subjects affected / exposed | 4 / 24 (16.67%) | 13 / 70 (18.57%) | 10 / 67 (14.93%) |
| occurrences (all) | 10 | 42 | 29 |
| Injection site discolouration | | | |
| subjects affected / exposed | 2 / 24 (8.33%) | 13 / 70 (18.57%) | 11 / 67 (16.42%) |
| occurrences (all) | 4 | 39 | 46 |
| Injection site discomfort | | | |
| subjects affected / exposed | 2 / 24 (8.33%) | 4 / 70 (5.71%) | 6 / 67 (8.96%) |
| occurrences (all) | 2 | 13 | 25 |
| Influenza like illness | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 2 / 70 (2.86%) | 2 / 67 (2.99%) |
| occurrences (all) | 0 | 2 | 3 |
| Injection site erythema | | | |
| subjects affected / exposed | 10 / 24 (41.67%) | 34 / 70 (48.57%) | 30 / 67 (44.78%) |
| occurrences (all) | 23 | 264 | 150 |
| Injection site haematoma | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 8 / 70 (11.43%) | 4 / 67 (5.97%) |
| occurrences (all) | 1 | 17 | 12 |
| Injection site haemorrhage | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hyperthermia | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Injection site erosion | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site hypoaesthesia | | | |

| | | | |
|-----------------------------|-----------------|------------------|------------------|
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site induration | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 6 / 70 (8.57%) | 7 / 67 (10.45%) |
| occurrences (all) | 1 | 20 | 16 |
| Injection site nodule | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 0 / 70 (0.00%) | 2 / 67 (2.99%) |
| occurrences (all) | 4 | 0 | 3 |
| Injection site pain | | | |
| subjects affected / exposed | 6 / 24 (25.00%) | 20 / 70 (28.57%) | 13 / 67 (19.40%) |
| occurrences (all) | 41 | 198 | 61 |
| Injection site pruritus | | | |
| subjects affected / exposed | 2 / 24 (8.33%) | 23 / 70 (32.86%) | 16 / 67 (23.88%) |
| occurrences (all) | 4 | 198 | 85 |
| Injection site swelling | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 10 / 70 (14.29%) | 7 / 67 (10.45%) |
| occurrences (all) | 0 | 69 | 44 |
| Injection site warmth | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 2 / 70 (2.86%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 39 | 34 |
| Malaise | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 3 / 70 (4.29%) | 3 / 67 (4.48%) |
| occurrences (all) | 1 | 3 | 4 |
| Nodule | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 2 / 67 (2.99%) |
| occurrences (all) | 0 | 1 | 2 |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 2 / 67 (2.99%) |
| occurrences (all) | 0 | 1 | 2 |
| Peripheral swelling | | | |

| | | | |
|---|-----------------|------------------|------------------|
| subjects affected / exposed | 1 / 24 (4.17%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Vaccination site pain | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Scar inflammation | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sensation of foreign body | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Swelling | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Pyrexia | | | |
| subjects affected / exposed | 4 / 24 (16.67%) | 15 / 70 (21.43%) | 17 / 67 (25.37%) |
| occurrences (all) | 5 | 23 | 38 |
| Immune system disorders | | | |
| Seasonal allergy | | | |
| subjects affected / exposed | 2 / 24 (8.33%) | 1 / 70 (1.43%) | 1 / 67 (1.49%) |
| occurrences (all) | 2 | 1 | 1 |
| Food allergy | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 1 | 1 |
| Immunodeficiency | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Type III immune complex mediated reaction | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Adenomyosis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Dysmenorrhoea | | | |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Breast pain | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cervical polyp | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cervix haemorrhage uterine | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Amenorrhoea | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Menstruation irregular | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Menstrual disorder | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Genital haemorrhage | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erectile dysfunction | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pelvic pain | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vulvovaginal swelling | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vulvovaginal inflammation | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vaginal discharge | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Catarrh | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Cough | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 2 / 67 (2.99%) |
| occurrences (all) | 0 | 1 | 2 |
| Dry throat | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Nasal pruritus | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal dryness | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperventilation | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal polyps | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reflux laryngitis | | | |

| | | | |
|--------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Productive cough | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 3 / 70 (4.29%) | 3 / 67 (4.48%) |
| occurrences (all) | 1 | 3 | 3 |
| Oropharyngeal discomfort | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Rhinitis allergic | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract inflammation | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stress | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sleep disorder | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Insomnia | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 2 / 67 (2.99%) |
| occurrences (all) | 0 | 1 | 2 |

| | | | |
|---|----------------------|------------------------|------------------------|
| Depression subjects affected / exposed occurrences (all) | 1 / 24 (4.17%) 1 | 0 / 70 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Depressed mood subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Investigations | | | |
| Activated partial thromboplastin time prolonged subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 1 / 67 (1.49%) 1 |
| Alanine aminotransferase increased subjects affected / exposed occurrences (all) | 4 / 24 (16.67%) 9 | 17 / 70 (24.29%) 25 | 15 / 67 (22.39%) 18 |
| Albumin urine present subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 1 / 70 (1.43%) 1 | 0 / 67 (0.00%) 0 |
| Antineutrophil cytoplasmic antibody positive subjects affected / exposed occurrences (all) | 2 / 24 (8.33%) 2 | 1 / 70 (1.43%) 1 | 3 / 67 (4.48%) 3 |
| Blood alkaline phosphatase increased subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 2 / 70 (2.86%) 3 | 1 / 67 (1.49%) 1 |
| Aspartate aminotransferase increased subjects affected / exposed occurrences (all) | 2 / 24 (8.33%) 4 | 8 / 70 (11.43%) 11 | 9 / 67 (13.43%) 12 |
| Autoantibody positive subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Bilirubin conjugated increased subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Antinuclear antibody positive subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Blood creatinine increased | | | |

| | | | |
|--------------------------------------|-----------------|-----------------|----------------|
| subjects affected / exposed | 0 / 24 (0.00%) | 2 / 70 (2.86%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Blood creatine increased | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood calcium decreased | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 1 | 1 |
| Blood potassium increased | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Complement factor C3 decreased | | | |
| subjects affected / exposed | 4 / 24 (16.67%) | 7 / 70 (10.00%) | 4 / 67 (5.97%) |
| occurrences (all) | 4 | 8 | 5 |
| C-reactive protein increased | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 3 / 70 (4.29%) | 2 / 67 (2.99%) |
| occurrences (all) | 0 | 3 | 2 |
| Body temperature increased | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 2 / 70 (2.86%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Blood pressure increased | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Complement factor C4 decreased | | | |
| subjects affected / exposed | 3 / 24 (12.50%) | 5 / 70 (7.14%) | 4 / 67 (5.97%) |
| occurrences (all) | 3 | 5 | 5 |
| Complement factor abnormal | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Complement factor increased | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 6 / 70 (8.57%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 6 | 1 |
| Creatinine renal clearance decreased | | | |

| | | | |
|--|----------------|----------------|----------------|
| subjects affected / exposed | 2 / 24 (8.33%) | 1 / 70 (1.43%) | 2 / 67 (2.99%) |
| occurrences (all) | 3 | 1 | 10 |
| Glomerular filtration rate decreased | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Eosinophil count increased | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Crystal urine present | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Creatinine urine increased | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| International normalised ratio increased | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immature granulocyte count increased | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hepatitis B DNA assay positive | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatic enzyme increased | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Liver function test abnormal | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Protein urine present | | | |

| | | | |
|--|----------------|-----------------|----------------|
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 1 | 1 |
| Platelet count decreased | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 8 / 70 (11.43%) | 3 / 67 (4.48%) |
| occurrences (all) | 0 | 11 | 6 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Mean cell volume decreased | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Total complement activity decreased | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Red blood cells urine positive | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Prothrombin time prolonged | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Transaminases increased | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| White blood cell count decreased | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Urine albumin/creatinine ratio | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Urine albumin/creatinine ratio increased | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urine analysis abnormal | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---------------------|---------------------|---------------------|
| Urine leukocyte esterase positive subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Urinary sediment present subjects affected / exposed occurrences (all) | 1 / 24 (4.17%) 1 | 0 / 70 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Injury, poisoning and procedural complications | | | |
| Eye injury | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Epicondylitis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Contusion | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 2 / 70 (2.86%) | 1 / 67 (1.49%) |
| occurrences (all) | 1 | 4 | 1 |
| Back injury | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthropod sting | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Animal bite | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Fall | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Post vaccination syndrome | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail injury | | | |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Muscle strain | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand fracture | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Foot fracture | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ligament sprain | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Skin abrasion | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 2 |
| Skin injury | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Sunburn | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Tooth avulsion | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth dislocation | | | |

| | | | |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Tooth fracture subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Tooth injury subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Vaccination complication subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 1 / 67 (1.49%) 1 |
| Congenital, familial and genetic disorders Dyschromatosis subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Cardiac disorders Supraventricular extrasystoles subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 1 / 67 (1.49%) 1 |
| Angina pectoris subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Atrial fibrillation subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 1 / 67 (1.49%) 1 |
| Palpitations subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 1 / 67 (1.49%) 1 |
| Tachycardia subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 1 / 70 (1.43%) 5 | 1 / 67 (1.49%) 1 |
| Nervous system disorders Ageusia subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Dizziness | | | |

| | | | |
|--------------------------------------|-----------------|------------------|------------------|
| subjects affected / exposed | 1 / 24 (4.17%) | 3 / 70 (4.29%) | 4 / 67 (5.97%) |
| occurrences (all) | 1 | 3 | 6 |
| Lethargy | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypoaesthesia | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 1 | 2 |
| Headache | | | |
| subjects affected / exposed | 4 / 24 (16.67%) | 14 / 70 (20.00%) | 14 / 67 (20.90%) |
| occurrences (all) | 4 | 25 | 50 |
| Dysgeusia | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Migraine | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Somnolence | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Sciatica | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral sensory neuropathy | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 2 / 70 (2.86%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |

| | | | |
|------------------------------|----------------|----------------|----------------|
| Abnormal clotting factor | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Increased tendency to bruise | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 2 / 70 (2.86%) | 2 / 67 (2.99%) |
| occurrences (all) | 0 | 2 | 2 |
| Leukocytosis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Leukopenia | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 3 / 70 (4.29%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Lymph node pain | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Eosinophilia | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Coagulopathy | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Lymphopenia | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Monocytosis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 4 / 70 (5.71%) | 2 / 67 (2.99%) |
| occurrences (all) | 0 | 5 | 2 |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| Polycythaemia | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Splenomegaly | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Thrombocytosis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 5 / 70 (7.14%) | 2 / 67 (2.99%) |
| occurrences (all) | 0 | 9 | 2 |
| Ear and labyrinth disorders | | | |
| Deafness | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vertigo positional | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Ear pain | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 2 / 70 (2.86%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 3 | 1 |
| Meniere's disease | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vertigo | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 2 / 70 (2.86%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Deafness neurosensory | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye disorders | | | |
| Asthenopia | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blepharitis | | | |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ocular hyperaemia | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye pain | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Keratitis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Noninfective conjunctivitis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dry eye | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periorbital swelling | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 1 / 70 (1.43%) | 1 / 67 (1.49%) |
| occurrences (all) | 1 | 2 | 1 |
| Abdominal distension | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 2 / 67 (2.99%) |
| occurrences (all) | 0 | 1 | 3 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 4 / 70 (5.71%) | 2 / 67 (2.99%) |
| occurrences (all) | 0 | 5 | 5 |
| Aphthous ulcer | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 3 / 70 (4.29%) | 3 / 67 (4.48%) |
| occurrences (all) | 0 | 4 | 3 |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| Abdominal tenderness | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Angular cheilitis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 2 / 70 (2.86%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 2 | 1 |
| Change of bowel habit | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 2 / 70 (2.86%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 2 | 1 |
| Dental caries | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 3 / 70 (4.29%) | 3 / 67 (4.48%) |
| occurrences (all) | 0 | 3 | 3 |
| Faeces discoloured | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dry mouth | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspepsia | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Faecaloma | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diverticulum intestinal | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|----------------------------------|----------------|----------------|----------------|
| Flatulence | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Food poisoning | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastritis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal sounds abnormal | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Haematochezia | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gingival bleeding | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Gingival pain | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival ulceration | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 1 | 1 |
| Haemorrhoidal haemorrhage | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Irritable bowel syndrome | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|---------------------|----------------------|---------------------|
| Large intestine polyp subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 1 / 70 (1.43%) 1 | 0 / 67 (0.00%) 0 |
| Tooth disorder subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Nausea subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 7 / 70 (10.00%) 9 | 4 / 67 (5.97%) 5 |
| Oesophageal spasm subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Stomatitis subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Mouth ulceration subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Toothache subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 3 / 70 (4.29%) 3 | 0 / 67 (0.00%) 0 |
| Vomiting subjects affected / exposed occurrences (all) | 1 / 24 (4.17%) 1 | 3 / 70 (4.29%) 3 | 0 / 67 (0.00%) 0 |
| Hepatobiliary disorders Gallbladder polyp subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 1 / 67 (1.49%) 1 |
| Hepatic cytolysis subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Hepatic function abnormal subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 1 / 70 (1.43%) 1 | 1 / 67 (1.49%) 3 |
| Hepatic steatosis | | | |

| | | | |
|--|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hypertransaminasaemia | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Hepatitis acute | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin and subcutaneous tissue disorders | | | |
| Alopecia | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 2 / 70 (2.86%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Acne | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Dermal cyst | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Blood blister | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Asteatosis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Angioedema | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry skin | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dermatitis allergic | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 2 |
| Dermatitis contact | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|----------------|----------------|----------------|
| Drug reaction with eosinophilia and systemic symptoms | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Haemorrhage subcutaneous | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 2 / 70 (2.86%) | 2 / 67 (2.99%) |
| occurrences (all) | 0 | 2 | 2 |
| Eczema | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ecchymosis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand dermatitis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Papule | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Night sweats | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail bed bleeding | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 3 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Petechiae | | | |

| | | | |
|-----------------------------|----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Pruritus | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 5 / 70 (7.14%) | 4 / 67 (5.97%) |
| occurrences (all) | 1 | 5 | 12 |
| Purpura | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rash | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 1 / 70 (1.43%) | 7 / 67 (10.45%) |
| occurrences (all) | 2 | 1 | 11 |
| Skin discolouration | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 1 | 3 |
| Rash pruritic | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Rash erythematous | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin hypertrophy | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin plaque | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Umbilical erythema | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Urticaria | | | |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 24 (0.00%) | 2 / 70 (2.86%) | 3 / 67 (4.48%) |
| occurrences (all) | 0 | 2 | 4 |
| Urticarial vasculitis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin hyperpigmentation | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| Cylindruria | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Albuminuria | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Leukocyturia | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Nephrocalcinosis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nephrolithiasis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Nephropathy toxic | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Proteinuria | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 2 / 70 (2.86%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 4 | 0 |
| Haematuria | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 3 / 70 (4.29%) | 3 / 67 (4.48%) |
| occurrences (all) | 2 | 3 | 3 |
| Glycosuria | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|----------------|----------------|----------------|
| Dysuria | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 1 | 1 |
| Ketonuria | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Renal cyst | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urine abnormality | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Endocrine disorders | | | |
| Hyperthyroidism | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypothyroidism | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Costochondritis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Arthritis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Back pain | | | |
| subjects affected / exposed | 2 / 24 (8.33%) | 4 / 70 (5.71%) | 4 / 67 (5.97%) |
| occurrences (all) | 2 | 6 | 4 |
| Bone swelling | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthralgia | | | |

| | | | |
|--------------------------------|-----------------|------------------|-----------------|
| subjects affected / exposed | 1 / 24 (4.17%) | 1 / 70 (1.43%) | 3 / 67 (4.48%) |
| occurrences (all) | 1 | 1 | 6 |
| Intervertebral disc protrusion | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint swelling | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Muscle spasms | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Muscle twitching | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Muscular weakness | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 0 / 70 (0.00%) | 2 / 67 (2.99%) |
| occurrences (all) | 1 | 0 | 3 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 1 | 1 |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 1 / 70 (1.43%) | 1 / 67 (1.49%) |
| occurrences (all) | 1 | 1 | 1 |
| Myalgia | | | |
| subjects affected / exposed | 3 / 24 (12.50%) | 10 / 70 (14.29%) | 7 / 67 (10.45%) |
| occurrences (all) | 3 | 12 | 10 |
| Flank pain | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 2 / 67 (2.99%) |
| occurrences (all) | 0 | 0 | 3 |
| Pain in extremity | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 4 / 70 (5.71%) | 3 / 67 (4.48%) |
| occurrences (all) | 1 | 4 | 6 |
| Osteoporosis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Spinal osteoarthritis | | | |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sjogren's syndrome | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sacral pain | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rotator cuff syndrome | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rheumatoid arthritis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Osteoarthritis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Tendonitis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Asymptomatic bacteriuria | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bacterial infection | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Bacteriuria | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| COVID-19 | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 3 / 70 (4.29%) | 6 / 67 (8.96%) |
| occurrences (all) | 1 | 3 | 6 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Chronic hepatitis B | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cystitis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 2 / 70 (2.86%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Diarrhoea infectious | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Epididymitis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Folliculitis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Genital herpes | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fungal skin infection | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Furuncle | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| Fungal infection | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gingivitis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Helicobacter gastritis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatitis B | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Herpes dermatitis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infection | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Herpes virus infection | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Hordeolum | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes simplex | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 2 / 67 (2.99%) |
| occurrences (all) | 0 | 5 | 2 |
| Injection site cellulitis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 4 / 70 (5.71%) | 2 / 67 (2.99%) |
| occurrences (all) | 1 | 6 | 2 |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| Oral herpes | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Oral infection | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Injection site abscess | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 2 / 70 (2.86%) | 2 / 67 (2.99%) |
| occurrences (all) | 0 | 4 | 2 |
| Otitis externa | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Parotitis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Periodontitis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 2 / 70 (2.86%) | 2 / 67 (2.99%) |
| occurrences (all) | 0 | 2 | 2 |
| Pustule | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|-----------------------------------|----------------|----------------|----------------|
| Respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Skin infection | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Suspected COVID-19 | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth abscess | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth infection | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urethritis | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | 3 / 70 (4.29%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 4 | 0 |
| Vaginal infection | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 1 / 70 (1.43%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 1 | 2 |

| | | | |
|---|---------------------|---------------------|----------------------|
| Vaginitis gardnerella subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 1 / 70 (1.43%) 1 | 0 / 67 (0.00%) 0 |
| Upper respiratory tract infection subjects affected / exposed occurrences (all) | 1 / 24 (4.17%) 1 | 3 / 70 (4.29%) 4 | 3 / 67 (4.48%) 4 |
| Viral upper respiratory tract infection subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Vulvovaginal candidiasis subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 2 / 70 (2.86%) 2 | 0 / 67 (0.00%) 0 |
| Metabolism and nutrition disorders | | | |
| Diabetes mellitus subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Decreased appetite subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 2 / 67 (2.99%) 15 |
| Cell death subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 0 / 70 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Hyperglycaemia subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 1 / 70 (1.43%) 1 | 0 / 67 (0.00%) 0 |
| Hypokalaemia subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 1 / 70 (1.43%) 1 | 0 / 67 (0.00%) 0 |
| Hypoglycaemia subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 1 / 70 (1.43%) 1 | 0 / 67 (0.00%) 0 |
| Hypocalcaemia subjects affected / exposed occurrences (all) | 0 / 24 (0.00%) 0 | 1 / 70 (1.43%) 1 | 0 / 67 (0.00%) 0 |
| Hyperkalaemia | | | |

| | | | |
|------------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Iron deficiency | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Polydipsia | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Vitamin B complex deficiency | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitamin D deficiency | | | |
| subjects affected / exposed | 0 / 24 (0.00%) | 0 / 70 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| Non-serious adverse events | GSK3228836+Placebo for 12WK (not on NA) | Placebo+GSK3228836 300mg for 12WK each (on NA) | |
|---|---|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 61 / 68 (89.71%) | 16 / 23 (69.57%) | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Uterine leiomyoma | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Skin papilloma | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Leiomyoma | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Haemangioma of liver | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Cervix carcinoma | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Neoplasm skin | | | |

| | | | |
|---|---------------------|---------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 23 (0.00%) 0 | |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Hot flush | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Hypotension | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Varicose vein | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Vasculitis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Vascular pain | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 7 / 68 (10.29%) | 0 / 23 (0.00%) | |
| occurrences (all) | 11 | 0 | |
| Chest discomfort | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Feeling abnormal | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Chills | | | |

| | | |
|-------------------------------|------------------|-----------------|
| subjects affected / exposed | 3 / 68 (4.41%) | 1 / 23 (4.35%) |
| occurrences (all) | 4 | 1 |
| Energy increased | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Fatigue | | |
| subjects affected / exposed | 8 / 68 (11.76%) | 1 / 23 (4.35%) |
| occurrences (all) | 11 | 1 |
| Chest pain | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Injection site anaesthesia | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 2 | 0 |
| Injection site bruising | | |
| subjects affected / exposed | 14 / 68 (20.59%) | 4 / 23 (17.39%) |
| occurrences (all) | 33 | 13 |
| Injection site discolouration | | |
| subjects affected / exposed | 6 / 68 (8.82%) | 2 / 23 (8.70%) |
| occurrences (all) | 37 | 3 |
| Injection site discomfort | | |
| subjects affected / exposed | 4 / 68 (5.88%) | 1 / 23 (4.35%) |
| occurrences (all) | 25 | 2 |
| Influenza like illness | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Injection site erythema | | |
| subjects affected / exposed | 37 / 68 (54.41%) | 5 / 23 (21.74%) |
| occurrences (all) | 179 | 22 |
| Injection site haematoma | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 1 / 23 (4.35%) |
| occurrences (all) | 3 | 2 |
| Injection site haemorrhage | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Hyperthermia | | |

| | | |
|------------------------------|------------------|-----------------|
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Injection site erosion | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Injection site hypoaesthesia | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Injection site induration | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 0 / 23 (0.00%) |
| occurrences (all) | 5 | 0 |
| Injection site nodule | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Injection site pain | | |
| subjects affected / exposed | 14 / 68 (20.59%) | 6 / 23 (26.09%) |
| occurrences (all) | 66 | 16 |
| Injection site pruritus | | |
| subjects affected / exposed | 19 / 68 (27.94%) | 2 / 23 (8.70%) |
| occurrences (all) | 98 | 3 |
| Injection site swelling | | |
| subjects affected / exposed | 5 / 68 (7.35%) | 1 / 23 (4.35%) |
| occurrences (all) | 13 | 2 |
| Injection site warmth | | |
| subjects affected / exposed | 4 / 68 (5.88%) | 0 / 23 (0.00%) |
| occurrences (all) | 19 | 0 |
| Malaise | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 2 / 23 (8.70%) |
| occurrences (all) | 0 | 3 |
| Nodule | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Non-cardiac chest pain | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Oedema peripheral | | |

| | | | |
|---|------------------|-----------------|--|
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pain | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Vaccination site pain | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 23 (4.35%) | |
| occurrences (all) | 0 | 1 | |
| Scar inflammation | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Sensation of foreign body | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Swelling | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Pyrexia | | | |
| subjects affected / exposed | 17 / 68 (25.00%) | 6 / 23 (26.09%) | |
| occurrences (all) | 23 | 7 | |
| Immune system disorders | | | |
| Seasonal allergy | | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 0 / 23 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Food allergy | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Immunodeficiency | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Type III immune complex mediated reaction | | | |

| | | | |
|--|---------------------|---------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 23 (0.00%) 0 | |
| Reproductive system and breast disorders | | | |
| Adenomyosis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Dysmenorrhoea | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Breast pain | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Cervical polyp | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Cervix haemorrhage uterine | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Amenorrhoea | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Menstruation irregular | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Menstrual disorder | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Genital haemorrhage | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Erectile dysfunction | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Pelvic pain | | | |

| | | | |
|---|----------------|----------------|--|
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Vulvovaginal swelling | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Vulvovaginal inflammation | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Vaginal discharge | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Catarrh | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Cough | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Dry throat | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Epistaxis | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Nasal pruritus | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Nasal dryness | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Nasal congestion | | | |

| | | | |
|--------------------------------------|----------------|----------------|--|
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Hyperventilation | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Nasal polyps | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Reflux laryngitis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Productive cough | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Oropharyngeal discomfort | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Rhinitis allergic | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Upper respiratory tract inflammation | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Stress | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |

| | | | |
|---|------------------|-----------------|--|
| Sleep disorder | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Irritability | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Insomnia | | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 0 / 23 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Depression | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Depressed mood | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Investigations | | | |
| Activated partial thromboplastin time prolonged | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 12 / 68 (17.65%) | 5 / 23 (21.74%) | |
| occurrences (all) | 21 | 5 | |
| Albumin urine present | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Antineutrophil cytoplasmic antibody positive | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 1 / 23 (4.35%) | |
| occurrences (all) | 1 | 1 | |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 7 / 68 (10.29%) | 3 / 23 (13.04%) | |
| occurrences (all) | 9 | 3 | |
| Autoantibody positive | | | |

| | | |
|--------------------------------|----------------|----------------|
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Bilirubin conjugated increased | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Antinuclear antibody positive | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Blood creatinine increased | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Blood creatine increased | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 23 (4.35%) |
| occurrences (all) | 0 | 1 |
| Blood calcium decreased | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Blood bilirubin increased | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Blood potassium increased | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Complement factor C3 decreased | | |
| subjects affected / exposed | 6 / 68 (8.82%) | 1 / 23 (4.35%) |
| occurrences (all) | 6 | 1 |
| C-reactive protein increased | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 23 (4.35%) |
| occurrences (all) | 0 | 1 |
| Body temperature increased | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 2 | 0 |
| Blood pressure increased | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Complement factor C4 decreased | | |

| | | |
|--|----------------|----------------|
| subjects affected / exposed | 4 / 68 (5.88%) | 1 / 23 (4.35%) |
| occurrences (all) | 4 | 1 |
| Complement factor abnormal | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Complement factor increased | | |
| subjects affected / exposed | 4 / 68 (5.88%) | 1 / 23 (4.35%) |
| occurrences (all) | 4 | 1 |
| Creatinine renal clearance decreased | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 1 / 23 (4.35%) |
| occurrences (all) | 3 | 1 |
| Glomerular filtration rate decreased | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 1 / 23 (4.35%) |
| occurrences (all) | 1 | 1 |
| Eosinophil count increased | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Crystal urine present | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 0 / 23 (0.00%) |
| occurrences (all) | 2 | 0 |
| Creatinine urine increased | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Gamma-glutamyltransferase increased | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| International normalised ratio increased | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Immature granulocyte count increased | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Hepatitis B DNA assay positive | | |

| | | |
|-------------------------------------|----------------|----------------|
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 23 (4.35%) |
| occurrences (all) | 0 | 1 |
| Hepatic enzyme increased | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Liver function test abnormal | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Protein urine present | | |
| subjects affected / exposed | 3 / 68 (4.41%) | 0 / 23 (0.00%) |
| occurrences (all) | 3 | 0 |
| Platelet count decreased | | |
| subjects affected / exposed | 3 / 68 (4.41%) | 1 / 23 (4.35%) |
| occurrences (all) | 3 | 1 |
| Neutrophil count decreased | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Mean cell volume decreased | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Total complement activity decreased | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Red blood cells urine positive | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Prothrombin time prolonged | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Transaminases increased | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| White blood cell count decreased | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 1 / 23 (4.35%) |
| occurrences (all) | 1 | 1 |
| Urine albumin/creatinine ratio | | |

| | | | |
|--|----------------|----------------|--|
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Urine albumin/creatinine ratio increased | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Urine analysis abnormal | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Urine leukocyte esterase positive | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 23 (4.35%) | |
| occurrences (all) | 0 | 1 | |
| Urinary sediment present | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Injury, poisoning and procedural complications | | | |
| Eye injury | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Epicondylitis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Contusion | | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 0 / 23 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Back injury | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Arthropod sting | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Animal bite | | | |

| | | |
|-----------------------------|----------------|----------------|
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Fall | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Post vaccination syndrome | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 1 / 23 (4.35%) |
| occurrences (all) | 1 | 1 |
| Nail injury | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Muscle strain | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Procedural pain | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Injury | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Hand fracture | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Foot fracture | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Ligament sprain | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Skin abrasion | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Skin injury | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Skin laceration | | |

| | | | |
|--|----------------|----------------|--|
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Sunburn | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Tooth avulsion | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Tooth dislocation | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Tooth fracture | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Tooth injury | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Vaccination complication | | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 0 / 23 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Congenital, familial and genetic disorders | | | |
| Dyschromatosis | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Cardiac disorders | | | |
| Supraventricular extrasystoles | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Angina pectoris | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Palpitations | | | |

| | | | |
|-------------------------------|------------------|-----------------|--|
| subjects affected / exposed | 2 / 68 (2.94%) | 0 / 23 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Tachycardia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Nervous system disorders | | | |
| Ageusia | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Dizziness | | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 0 / 23 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Lethargy | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Hypoaesthesia | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Headache | | | |
| subjects affected / exposed | 14 / 68 (20.59%) | 3 / 23 (13.04%) | |
| occurrences (all) | 26 | 3 | |
| Dysgeusia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Migraine | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Somnolence | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Sciatica | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Peripheral sensory neuropathy | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |

| | | | |
|--------------------------------------|----------------|----------------|--|
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Syncope | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 1 / 23 (4.35%) | |
| occurrences (all) | 1 | 1 | |
| Abnormal clotting factor | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Increased tendency to bruise | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Leukocytosis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Leukopenia | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Lymph node pain | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Eosinophilia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Coagulopathy | | | |

| | | | |
|-----------------------------|----------------|----------------|--|
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Lymphopenia | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Monocytosis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Neutropenia | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Polycythaemia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Splenomegaly | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Thrombocytosis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Thrombocytopenia | | | |
| subjects affected / exposed | 3 / 68 (4.41%) | 0 / 23 (0.00%) | |
| occurrences (all) | 5 | 0 | |
| Ear and labyrinth disorders | | | |
| Deafness | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Vertigo positional | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Ear pain | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Meniere's disease | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |

| | | | |
|-----------------------------|----------------|----------------|--|
| Vertigo | | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 0 / 23 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Deafness neurosensory | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Eye disorders | | | |
| Asthenopia | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Blepharitis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Ocular hyperaemia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Eye pain | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Keratitis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Noninfective conjunctivitis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Dry eye | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Periorbital swelling | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Abdominal distension | | | |

| | | |
|-----------------------------|----------------|----------------|
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Abdominal pain | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 1 / 23 (4.35%) |
| occurrences (all) | 1 | 1 |
| Aphthous ulcer | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Abdominal pain upper | | |
| subjects affected / exposed | 3 / 68 (4.41%) | 0 / 23 (0.00%) |
| occurrences (all) | 4 | 0 |
| Abdominal tenderness | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Angular cheilitis | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Abdominal pain lower | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Change of bowel habit | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Constipation | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Dental caries | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 23 (4.35%) |
| occurrences (all) | 0 | 1 |
| Diarrhoea | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 1 / 23 (4.35%) |
| occurrences (all) | 2 | 1 |
| Faeces discoloured | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Dry mouth | | |

| | | |
|----------------------------------|----------------|----------------|
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Dyspepsia | | |
| subjects affected / exposed | 3 / 68 (4.41%) | 0 / 23 (0.00%) |
| occurrences (all) | 3 | 0 |
| Faecaloma | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Diverticulum intestinal | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Flatulence | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Food poisoning | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Gastritis | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Gastrointestinal sounds abnormal | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Haematochezia | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Gingival bleeding | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Gingival pain | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Gingival ulceration | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Gastrooesophageal reflux disease | | |

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|-----------------------------|----------------|----------------|--|
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Haemorrhoidal haemorrhage | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Irritable bowel syndrome | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Large intestine polyp | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Tooth disorder | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Nausea | | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 1 / 23 (4.35%) | |
| occurrences (all) | 2 | 1 | |
| Oesophageal spasm | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Stomatitis | | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 0 / 23 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Mouth ulceration | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Toothache | | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 1 / 23 (4.35%) | |
| occurrences (all) | 3 | 1 | |
| Vomiting | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 1 / 23 (4.35%) | |
| occurrences (all) | 1 | 2 | |
| Hepatobiliary disorders | | | |

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|--|----------------|----------------|--|
| Gallbladder polyp | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Hepatic cytolysis | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Hepatic function abnormal | | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 1 / 23 (4.35%) | |
| occurrences (all) | 2 | 1 | |
| Hepatic steatosis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Hypertransaminasaemia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Hepatitis acute | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Alopecia | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Acne | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Dermal cyst | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Blood blister | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Asteatosis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Angioedema | | | |

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| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Dry skin | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Dermatitis allergic | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Dermatitis contact | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Drug reaction with eosinophilia and systemic symptoms | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Dermatitis | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Haemorrhage subcutaneous | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Erythema | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 1 / 23 (4.35%) |
| occurrences (all) | 6 | 1 |
| Eczema | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 0 / 23 (0.00%) |
| occurrences (all) | 2 | 0 |
| Ecchymosis | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 23 (4.35%) |
| occurrences (all) | 0 | 1 |
| Hand dermatitis | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Papule | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |

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|-----------------------------|----------------|----------------|
| Night sweats | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Nail bed bleeding | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Hyperhidrosis | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Petechiae | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Pruritus | | |
| subjects affected / exposed | 3 / 68 (4.41%) | 1 / 23 (4.35%) |
| occurrences (all) | 7 | 1 |
| Purpura | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Rash | | |
| subjects affected / exposed | 5 / 68 (7.35%) | 0 / 23 (0.00%) |
| occurrences (all) | 13 | 0 |
| Skin discolouration | | |
| subjects affected / exposed | 3 / 68 (4.41%) | 0 / 23 (0.00%) |
| occurrences (all) | 4 | 0 |
| Rash macular | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Rash maculo-papular | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Rash pruritic | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Rash erythematous | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |

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|-----------------------------|----------------|----------------|--|
| Skin hypertrophy | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Skin plaque | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Umbilical erythema | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Urticaria | | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 1 / 23 (4.35%) | |
| occurrences (all) | 2 | 1 | |
| Urticarial vasculitis | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Skin hyperpigmentation | | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 0 / 23 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Renal and urinary disorders | | | |
| Cylindruria | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Albuminuria | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Leukocyturia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Nephrocalcinosis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Nephropathy toxic | | | |

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|---|----------------|----------------|--|
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Proteinuria | | | |
| subjects affected / exposed | 3 / 68 (4.41%) | 0 / 23 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Haematuria | | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 0 / 23 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Glycosuria | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Dysuria | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Ketonuria | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Renal cyst | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Urine abnormality | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Endocrine disorders | | | |
| Hyperthyroidism | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Hypothyroidism | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Musculoskeletal and connective tissue disorders | | | |

| | | |
|--------------------------------|----------------|----------------|
| Costochondritis | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Arthritis | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Back pain | | |
| subjects affected / exposed | 3 / 68 (4.41%) | 0 / 23 (0.00%) |
| occurrences (all) | 5 | 0 |
| Bone swelling | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Arthralgia | | |
| subjects affected / exposed | 4 / 68 (5.88%) | 1 / 23 (4.35%) |
| occurrences (all) | 5 | 1 |
| Intervertebral disc protrusion | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Joint swelling | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Muscle spasms | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 23 (4.35%) |
| occurrences (all) | 0 | 1 |
| Muscle twitching | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Muscular weakness | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Musculoskeletal pain | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Musculoskeletal stiffness | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 23 (4.35%) |
| occurrences (all) | 0 | 1 |

| | | |
|-----------------------------|----------------|----------------|
| Myalgia | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 0 / 23 (0.00%) |
| occurrences (all) | 2 | 0 |
| Flank pain | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Pain in extremity | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 0 / 23 (0.00%) |
| occurrences (all) | 2 | 0 |
| Osteoporosis | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Spinal osteoarthritis | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Sjogren's syndrome | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Sacral pain | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Rotator cuff syndrome | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Rheumatoid arthritis | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Neck pain | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Osteoarthritis | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Tendonitis | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |

| | | | |
|---|---------------------|---------------------|--|
| Infections and infestations Asymptomatic bacteriuria subjects affected / exposed occurrences (all) | 2 / 68 (2.94%) 2 | 0 / 23 (0.00%) 0 | |
| Bacterial infection subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 23 (0.00%) 0 | |
| Bacteriuria subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 23 (0.00%) 0 | |
| Conjunctivitis subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 23 (0.00%) 0 | |
| COVID-19 subjects affected / exposed occurrences (all) | 4 / 68 (5.88%) 4 | 1 / 23 (4.35%) 1 | |
| Cellulitis subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 23 (0.00%) 0 | |
| Chronic hepatitis B subjects affected / exposed occurrences (all) | 1 / 68 (1.47%) 1 | 0 / 23 (0.00%) 0 | |
| Bronchitis subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 23 (0.00%) 0 | |
| Cystitis subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 23 (0.00%) 0 | |
| Diarrhoea infectious subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 23 (0.00%) 0 | |
| Epididymitis subjects affected / exposed occurrences (all) | 0 / 68 (0.00%) 0 | 0 / 23 (0.00%) 0 | |
| Folliculitis | | | |

| | | |
|-----------------------------|----------------|----------------|
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Genital herpes | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Fungal skin infection | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Furuncle | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Gastroenteritis | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Fungal infection | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Gingivitis | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Helicobacter gastritis | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Hepatitis B | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Herpes dermatitis | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Infection | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Herpes virus infection | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Herpes zoster | | |

| | | |
|-----------------------------|----------------|-----------------|
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Hordeolum | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Herpes simplex | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Injection site cellulitis | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Nasopharyngitis | | |
| subjects affected / exposed | 4 / 68 (5.88%) | 4 / 23 (17.39%) |
| occurrences (all) | 6 | 4 |
| Oral herpes | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 0 / 23 (0.00%) |
| occurrences (all) | 2 | 0 |
| Oral infection | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Injection site abscess | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 23 (4.35%) |
| occurrences (all) | 0 | 1 |
| Otitis media | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Otitis media acute | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Influenza | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Otitis externa | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Parotitis | | |

| | | |
|-----------------------------------|----------------|----------------|
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Periodontitis | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 0 / 23 (0.00%) |
| occurrences (all) | 3 | 0 |
| Pharyngitis | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Pustule | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Subcutaneous abscess | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Respiratory tract infection viral | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 2 | 0 |
| Sinusitis | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Skin infection | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Respiratory tract infection | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 23 (4.35%) |
| occurrences (all) | 0 | 1 |
| Suspected COVID-19 | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Tonsillitis | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 |
| Tooth abscess | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 |
| Tooth infection | | |

| | | | |
|---|----------------|----------------|--|
| subjects affected / exposed | 2 / 68 (2.94%) | 0 / 23 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Viral infection | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Urethritis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 4 / 68 (5.88%) | 0 / 23 (0.00%) | |
| occurrences (all) | 4 | 0 | |
| Vaginal infection | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Vaginitis gardnerella | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 2 / 68 (2.94%) | 0 / 23 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Vulvovaginal candidiasis | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Metabolism and nutrition disorders | | | |
| Diabetes mellitus | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Decreased appetite | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 1 / 23 (4.35%) | |
| occurrences (all) | 1 | 1 | |
| Cell death | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |

| | | | |
|------------------------------|----------------|----------------|--|
| Hyperglycaemia | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Hypokalaemia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Hypocalcaemia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Hyperkalaemia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 1 / 23 (4.35%) | |
| occurrences (all) | 0 | 1 | |
| Iron deficiency | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Polydipsia | | | |
| subjects affected / exposed | 0 / 68 (0.00%) | 0 / 23 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Vitamin B complex deficiency | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Vitamin D deficiency | | | |
| subjects affected / exposed | 1 / 68 (1.47%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 0 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-------------------|-------------------|
| 09 April 2020 | Original Protocol |
| 10 May 2021 | Amendment 01 |
| 23 September 2021 | Amendment 02 |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported