



Clinical trial results:

A Phase 3 Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of MEDI8897, a Monoclonal Antibody with an Extended Half-life Against Respiratory Syncytial Virus, in Healthy Late Preterm and Term Infants (MELODY)

Summary

| | |
|--------------------------|--|
| EudraCT number | 2019-000114-11 |
| Trial protocol | BE LV GB SE FR DE CZ LT EE FI PL AT ES BG IT |
| Global end of trial date | 20 June 2023 |

Results information

| | |
|--------------------------------|-------------------|
| Result version number | v1 (current) |
| This version publication date | 22 September 2023 |
| First version publication date | 22 September 2023 |

Trial information

Trial identification

| | |
|-----------------------|-------------|
| Sponsor protocol code | D5290C00004 |
|-----------------------|-------------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | AstraZeneca |
| Sponsor organisation address | 950 Wind River Ln, Gaithersburg, United States, MD 20878 |
| Public contact | Global Clinical Lead, AstraZeneca, +1 8772409479, information.center@astrazeneca.com |
| Scientific contact | Global Clinical Lead, AstraZeneca, +1 8772409479, information.center@astrazeneca.com |

Notes:

Paediatric regulatory details

| | |
|--|---------------------|
| Is trial part of an agreed paediatric investigation plan (PIP) | Yes |
| EMA paediatric investigation plan number(s) | EMA-001794-PIP01-15 |
| 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? | Yes |

Notes:

Results analysis stage

| | |
|--|--------------|
| Analysis stage | Final |
| Date of interim/final analysis | 06 June 2023 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 28 June 2021 |
| Global end of trial reached? | Yes |
| Global end of trial date | 20 June 2023 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy of nirsevimab when administered as a single fixed IM dose to term/late preterm infants \geq 35 weeks 0 days GA and entering their first RSV season, in reducing MA RSV LRTI, compared to placebo

Protection of trial subjects:

Each subject was assigned a SID to ensure that personally identifiable information was kept separate from the study data. Subject data that were relevant to the trial, eg, demographic information, physical or mental health condition, diagnosis, comorbidities, laboratory test results, etc. were collected with the subject's informed consent.

The IRB/IEC responsible for each site must review and approve the final study protocol, including the final version of the Informed Consent Form and any other written information and/or materials to be provided to the subjects. The IRB/IEC must also approve all advertising used to recruit subjects for the study.

Before the study was initiated, AstraZeneca/MedImmune ensured that the national regulatory authority in each country had been notified and their approval had been obtained, as required.

AstraZeneca/MedImmune provided safety updates/reports according to local requirements, including suspected unexpected serious adverse reactions where relevant, to regulatory authorities, IRB/IEC, and principal investigators.

Background therapy:

MEDI8897 is a recombinant human immunoglobulin G1 kappa (IgG1 κ) monoclonal antibody (mAb) directed against the prefusion conformation of the RSV fusion (F) protein. The antibody has been engineered with a triple amino acid substitution (YTE; M257Y/S259T/T261E [M252Y/S254T/T256E, according to the European Union (EU) numbering system]) in the fragment crystallizable (Fc) region to prolong the t_{1/2}, which is expected to provide protection from serious RSV disease for the duration of the RSV season. MEDI8897 neutralizes RSV by binding the prefusion conformation of the RSV F protein at a site distinct from that bound by palivizumab. In preclinical studies, MEDI8897 was > 150 fold more potent than palivizumab in vitro and approximately 9-fold more potent than palivizumab in vivo in the cotton rat model. MEDI8897 is currently under development by MedImmune for the passive immunization of all infants entering their first RSV season and children with CLD or CHD entering their first and second RSV season for the prevention of LRTI caused by RSV. MEDI8897 may provide a cost effective opportunity to protect all infants from RSV disease based on an improvement in potency and the extended t_{1/2} that is expected to support once-per-RSV-season dosing.

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 23 July 2019 |
| Long term follow-up planned | Yes |
| Long term follow-up rationale | Safety, Efficacy |
| Long term follow-up duration | 17 Months |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|------------------------|
| Country: Number of subjects enrolled | Austria: 8 |
| Country: Number of subjects enrolled | Belgium: 14 |
| Country: Number of subjects enrolled | Bulgaria: 131 |
| Country: Number of subjects enrolled | Canada: 13 |
| Country: Number of subjects enrolled | Czechia: 29 |
| Country: Number of subjects enrolled | Estonia: 73 |
| Country: Number of subjects enrolled | Finland: 44 |
| Country: Number of subjects enrolled | France: 30 |
| Country: Number of subjects enrolled | Germany: 58 |
| Country: Number of subjects enrolled | Israel: 44 |
| Country: Number of subjects enrolled | Italy: 7 |
| Country: Number of subjects enrolled | Japan: 147 |
| Country: Number of subjects enrolled | Korea, Republic of: 2 |
| Country: Number of subjects enrolled | Latvia: 50 |
| Country: Number of subjects enrolled | Lithuania: 57 |
| Country: Number of subjects enrolled | Mexico: 1 |
| Country: Number of subjects enrolled | Panama: 505 |
| Country: Number of subjects enrolled | Poland: 58 |
| Country: Number of subjects enrolled | Russian Federation: 93 |
| Country: Number of subjects enrolled | Spain: 213 |
| Country: Number of subjects enrolled | Sweden: 32 |
| Country: Number of subjects enrolled | Turkey: 16 |
| Country: Number of subjects enrolled | Ukraine: 34 |
| Country: Number of subjects enrolled | United Kingdom: 8 |
| Country: Number of subjects enrolled | United States: 558 |
| Country: Number of subjects enrolled | Argentina: 178 |
| Country: Number of subjects enrolled | Australia: 27 |
| Country: Number of subjects enrolled | Chile: 45 |
| Country: Number of subjects enrolled | Colombia: 54 |
| Country: Number of subjects enrolled | New Zealand: 21 |
| Country: Number of subjects enrolled | South Africa: 462 |
| Worldwide total number of subjects | 3012 |
| EEA total number of subjects | 804 |

Notes:

Subjects enrolled per age group

| | |
|--|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 | 0 |

| | |
|--|------|
| wk | |
| Newborns (0-27 days) | 655 |
| Infants and toddlers (28 days-23 months) | 2357 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

The study was planned to recruit around 3000 infants. The impact of the COVID-19 pandemic on RSV circulation led to the decision to analyze the primary endpoint on the first 1500 subjects (Primary Cohort). Then the study restarted to recruit and the study comprised 2 cohorts: Primary and Safety for a total of 3319 screened subjects

Pre-assignment

Screening details:

In Primary Cohort: 1626 screened subjects and 136 subjects failing screening criteria.

Overall 3319 screened subjects and 307 subjects failing screening criteria.

Period 1

| | |
|------------------------------|---|
| Period 1 title | All Subjects |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Monitor, Data analyst, Carer, Assessor |

Arms

| | |
|------------------------------|---------|
| Are arms mutually exclusive? | Yes |
| Arm title | Placebo |

Arm description:

Placebo in All Subjects

| | |
|--|------------------------|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Commercially available 0.9% (w/v)
saline (sterile for human use)

| | |
|------------------|----------|
| Arm title | Medi9987 |
|------------------|----------|

Arm description:

Medi9987 in All Subjects

| | |
|--|------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Nirsevimab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Single IM dose of 50 mg (if < 5 kg weight at time of dosing) or 100 mg (if ≥ 5 kg weight at time of dosing)

| Number of subjects in period 1 | Placebo | Medi9987 |
|--------------------------------|---------|----------|
| Started | 1003 | 2009 |
| Completed Day 151 Follow up | 985 | 1977 |
| Completed Day 361 Follow up | 967 | 1944 |
| Completed | 923 | 1873 |
| Not completed | 80 | 136 |
| Adverse event, serious fatal | - | 5 |
| Consent withdrawn by subject | 35 | 44 |
| Other | 16 | 23 |
| Covid 19 Pandemic | 1 | 3 |
| Lost to follow-up | 28 | 61 |

Period 2

| | |
|------------------------------|---|
| Period 2 title | Primary Cohort |
| Is this the baseline period? | Yes ^[1] |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Monitor, Data analyst, Carer, Assessor |

Arms

| | |
|------------------------------|---------|
| Are arms mutually exclusive? | Yes |
| Arm title | Placebo |

Arm description:

Placebo in Primary Cohort

| | |
|--|------------------------|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Commercially available 0.9% (w/v)
saline (sterile for human use)

| | |
|------------------|----------|
| Arm title | Medi9987 |
|------------------|----------|

Arm description:

Medi9987 in Primary Cohort

| | |
|--|------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Nirsevimab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Single IM dose of 50 mg (if < 5 kg weight at time of

dosing) or 100 mg (if ≥ 5 kg weight at time of dosing)

Notes:

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

Justification: Primary cohort is the baseline period for the primary efficacy analysis

| Number of subjects in period 2^[2][3] | Placebo | Medi9987 |
|--|---------|----------|
| Started | 496 | 994 |
| Complete Day 151 Follow Up | 488 | 977 |
| Complete Day 361 Follow UP | 453 | 914 |
| Completed | 43 | 89 |
| Not completed | 453 | 905 |
| Adverse event, serious fatal | - | 4 |
| Consent withdrawn by subject | 14 | 20 |
| Other | 3 | 4 |
| Ongoing at the DCO | 432 | 865 |
| Covid 19 Pandemic | 1 | 3 |
| Lost to follow-up | 3 | 9 |

Notes:

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

Justification: Primary cohort is a subset of the All subjects population

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

Justification: Primary cohort is a subset of the All subjects population

Baseline characteristics

Reporting groups

| | |
|--|----------|
| Reporting group title | Placebo |
| Reporting group description: Placebo in Primary Cohort | |
| Reporting group title | Medi9987 |
| Reporting group description: Medi9987 in Primary Cohort | |

| Reporting group values | Placebo | Medi9987 | Total |
|--|----------|----------|-------|
| Number of subjects | 496 | 994 | 1490 |
| Age Categorical | | | |
| Age in months at randomization in Primary Cohort | | | |
| Units: Subjects | | | |
| ≤ 3 months | 285 | 577 | 862 |
| > 3 months - ≤ 6 months | 162 | 317 | 479 |
| ≥ 6 months | 49 | 100 | 149 |
| Age Continuous | | | |
| Age (months) at randomization | | | |
| Units: months | | | |
| arithmetic mean | 3.012 | 2.912 | |
| standard deviation | ± 2.2520 | ± 2.946 | - |
| Gender Categorical | | | |
| Gender in the Primary Cohort | | | |
| Units: Subjects | | | |
| Male | 239 | 530 | 769 |
| Female | 257 | 464 | 721 |

End points

End points reporting groups

| | |
|--|----------|
| Reporting group title | Placebo |
| Reporting group description: Placebo in All Subjects | |
| Reporting group title | Medi9987 |
| Reporting group description: Medi9987 in All Subjects | |
| Reporting group title | Placebo |
| Reporting group description: Placebo in Primary Cohort | |
| Reporting group title | Medi9987 |
| Reporting group description: Medi9987 in Primary Cohort | |

Primary: Incidence of MA RSV LRTI Through 150 Days Post Dose (Primary Cohort)

| | |
|--|--|
| End point title | Incidence of MA RSV LRTI Through 150 Days Post Dose (Primary Cohort) |
| End point description: Primary Endpoint Analysed on Primary Cohort Through 150 Days (N=1490 Participants) | |
| End point type | Primary |
| End point timeframe: Through 150 Days Post Dose | |

| End point values | Placebo | Medi9987 | | |
|--|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 496 | 994 | | |
| Units: Participants | | | | |
| Observed events through day 150 post dose | 25 | 12 | | |
| Subjects requiring imputation | 6 | 15 | | |
| Subjects without event through day 150 post dose | 465 | 967 | | |

Statistical analyses

| | |
|---|----------------------------------|
| Statistical analysis title | Relative Risk Reduction Analysis |
| Statistical analysis description: Relative risk reduction of nirsevimab versus placebo, the 95% CI and p-value were estimated based on Poisson regression with robust variance (including stratification factor [age at randomisation] as covariate) obtained after missing data imputation. | |
| Comparison groups | Placebo v Medi9987 |

| | |
|---|-------------------------|
| Number of subjects included in analysis | 1490 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Poisson Model |
| Parameter estimate | Relative Risk Reduction |
| Point estimate | 74.53 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 49.63 |
| upper limit | 87.12 |

Secondary: Incidence of MA RSV LRTI with Hospitalisation Through 150 Days Post Dose (Primary Cohort)

| | |
|---|---|
| End point title | Incidence of MA RSV LRTI with Hospitalisation Through 150 Days Post Dose (Primary Cohort) |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| Hospitalization Analysed on Primary Cohort Through 150 Days (N=1490 Participants) | |

| End point values | Placebo | Medi9987 | | |
|--|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 496 | 994 | | |
| Units: Participants | | | | |
| Observed events through day 150 post dose | 6 | 8 | | |
| Subjects requiring imputation | 15 | 6 | | |
| Subjects without event through day 150 post dose | 973 | 482 | | |

Statistical analyses

| | |
|--|----------------------------------|
| Statistical analysis title | Relative Risk Reduction Analysis |
| Statistical analysis description: | |
| Relative risk reduction of nirsevimab versus placebo, the 95% CI and p-value were estimated based on Poisson regression with robust variance (including study as covariate for pooled studies) obtained after missing data imputation. | |
| Comparison groups | Medi9987 v Placebo |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 1490 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0708 |
| Method | Poisson Regression Model |
| Parameter estimate | Relative Risk Reduction |
| Point estimate | 62.15 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -8.57 |
| upper limit | 86.8 |

Other pre-specified: Disease Incidence from the 2nd RSV Season (All Subjects)

| | |
|-----------------------------------|--|
| End point title | Disease Incidence from the 2nd RSV Season (All Subjects) |
| End point description: | |
| End point type | Other pre-specified |
| End point timeframe: | |
| From Day 361 to Day 510 Post Dose | |

| End point values | Placebo | Medi9987 | | |
|--|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 967 | 1944 | | |
| Units: Participants | | | | |
| MA RSV LRTI (protocol defined) | 10 | 19 | | |
| MA RSV LRTI hospitalization (protocol defined) | 3 | 3 | | |

Statistical analyses

No statistical analyses for this end point

Post-hoc: Incidence of MA RSV LRTI Through 150 Days Post Dose (All Subjects)

| | |
|--|--|
| End point title | Incidence of MA RSV LRTI Through 150 Days Post Dose (All Subjects) |
| End point description: | |
| Primary Endpoint Analysed on All Subjects Through 150 Days (N=3012 participants) | |
| End point type | Post-hoc |
| End point timeframe: | |
| Through 150 Days Post Dose | |

| End point values | Placebo | Medi9987 | | |
|--|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 1003 | 2009 | | |
| Units: Participants | | | | |
| Observed events | 54 | 24 | | |
| Subjects requiring imputation | 17 | 31 | | |
| Subjects without event through day 150 post dose | 932 | 1954 | | |

Statistical analyses

| Statistical analysis title | Relative Risk Reduction Analysis |
|--|----------------------------------|
| Statistical analysis description: | |
| Relative risk reduction of nirsevimab versus placebo, the 95% CI and p-value were estimated based on Poisson regression with robust variance (including stratification factor [age at randomisation] as covariate) obtained after missing data imputation. | |
| Comparison groups | Placebo v Medi9987 |
| Number of subjects included in analysis | 3012 |
| Analysis specification | Post-hoc |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Poisson regression model |
| Parameter estimate | Relative Risk Reduction (RRR) |
| Point estimate | 76.36 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 62.27 |
| upper limit | 85.18 |

Post-hoc: Incidence of MA RSV LRTI with Hospitalisation Through 150 Days Post Dose (All Subjects)

| | |
|---|---|
| End point title | Incidence of MA RSV LRTI with Hospitalisation Through 150 Days Post Dose (All Subjects) |
| End point description: | |
| Hospitalization Analysed on All Subjects Through 150 Days (N=3012 participants) | |
| End point type | Post-hoc |
| End point timeframe: | |
| Through 150 Days Post Dose | |

| End point values | Placebo | Medi9987 | | |
|--|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 1003 | 2009 | | |
| Units: Participants | | | | |
| Observed events through day 150 post dose | 20 | 9 | | |
| Subjects requiring imputation | 18 | 31 | | |
| Subjects without event through day 150 post dose | 965 | 1969 | | |

Statistical analyses

| Statistical analysis title | Relative Risk Reduction Analysis |
|---|----------------------------------|
| Statistical analysis description: | |
| RRR of Medi8897 versus placebo; 95% CI and p-value estimated with Poisson regression with robust variance (including stratification factors [age at randomisation] as covariate) obtained after multiple imputation | |
| Comparison groups | Placebo v Medi9987 |
| Number of subjects included in analysis | 3012 |
| Analysis specification | Post-hoc |
| Analysis type | superiority |
| P-value | = 0.0002 |
| Method | Poisson model |
| Parameter estimate | Relative Risk Reduction (RRR) |
| Point estimate | 76.84 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 49.36 |
| upper limit | 89.41 |

Adverse events

Adverse events information

Timeframe for reporting adverse events:
through 360 days post dose

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

Dictionary used

| | |
|--------------------|------------|
| Dictionary name | MedDRA |
| Dictionary version | MedDRA25.1 |

Reporting groups

| | |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description:
Placebo (All Subjects)

| | |
|-----------------------|----------|
| Reporting group title | MEDI8897 |
|-----------------------|----------|

Reporting group description:
MEDI8897 (All Subjects)

| Serious adverse events | Placebo | MEDI8897 | |
|--|------------------|--------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 83 / 997 (8.32%) | 149 / 1997 (7.46%) | |
| number of deaths (all causes) | 0 | 5 | |
| number of deaths resulting from adverse events | 0 | 4 | |
| Vascular disorders | | | |
| Shock | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Kawasaki's disease | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 2 / 1997 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pregnancy, puerperium and perinatal conditions | | | |
| Jaundice neonatal | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General disorders and administration site conditions | | | |

| | | | |
|---|-----------------|------------------|--|
| Pyrexia | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 6 / 1997 (0.30%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fever neonatal | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Death | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Immune system disorders | | | |
| Milk allergy | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aspiration | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Apnoea | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|-----------------|------------------|--|
| Psychiatric disorders | | | |
| Staring | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sleep terror | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Behavioural insomnia of childhood | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury, poisoning and procedural complications | | | |
| Thermal burn | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skull fractured base | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Head injury | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hand fracture | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femur fracture | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|-----------------|------------------|--|
| Fall | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Concussion | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Accidental exposure to product by child | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Accidental overdose | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Burns third degree | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Congenital, familial and genetic disorders | | | |
| Pyloric stenosis | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Phenylketonuria | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchogenic cyst | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|-----------------|------------------|--|
| Nervous system disorders | | | |
| Febrile convulsion | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 4 / 1997 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Facial paralysis | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Idiopathic generalised epilepsy | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypotonia | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subarachnoid haemorrhage | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seizure | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 2 / 1997 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood and lymphatic system disorders | | | |
| Hypochromic anaemia | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Colitis | | | |

| | | | |
|---|-----------------|------------------|--|
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Constipation | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 3 / 1997 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enteritis | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Food poisoning | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Allergic gastroenteritis | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Allergic colitis | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrooesophageal reflux disease | | | |

| | | | |
|---|-----------------|------------------|--|
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vomiting | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal obstruction | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Impaired gastric emptying | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Jaundice | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholelithiasis | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Petechiae | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Scoliosis | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|-------------------------------------|--------------------------------------|--|
| Infections and infestations COVID-19 pneumonia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 997 (0.10%) 0 / 1 0 / 0 | 1 / 1997 (0.05%) 0 / 1 0 / 0 | |
| Abscess limb subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 997 (0.10%) 0 / 1 0 / 0 | 0 / 1997 (0.00%) 0 / 0 0 / 0 | |
| Abscess neck subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 997 (0.00%) 0 / 0 0 / 0 | 1 / 1997 (0.05%) 0 / 1 0 / 0 | |
| Abscess of external auditory meatus subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 997 (0.10%) 0 / 1 0 / 0 | 0 / 1997 (0.00%) 0 / 0 0 / 0 | |
| Adenoviral upper respiratory infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 997 (0.00%) 0 / 0 0 / 0 | 3 / 1997 (0.15%) 0 / 3 0 / 0 | |
| Bacterial sepsis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 997 (0.10%) 0 / 1 0 / 0 | 0 / 1997 (0.00%) 0 / 0 0 / 0 | |
| Botulism subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 997 (0.00%) 0 / 0 0 / 0 | 1 / 1997 (0.05%) 0 / 1 0 / 0 | |
| Bronchiolitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 17 / 997 (1.71%) 0 / 18 0 / 0 | 27 / 1997 (1.35%) 0 / 28 0 / 0 | |

| | | | |
|---|-----------------|------------------|--|
| COVID-19 | | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 3 / 1997 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis viral | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis | | | |
| subjects affected / exposed | 4 / 997 (0.40%) | 3 / 1997 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cellulitis | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Conjunctivitis viral | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterovirus infection | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia pyelonephritis | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia urinary tract infection | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Exanthema subitum | | | |

| | | | |
|---|-----------------|-------------------|--|
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis | | | |
| subjects affected / exposed | 5 / 997 (0.50%) | 14 / 1997 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 15 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Gastroenteritis Escherichia coli | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis adenovirus | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis clostridial | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis norovirus | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis rotavirus | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 2 / 1997 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hand-foot-and-mouth disease | | | |

| | | | |
|---|-----------------|------------------|--|
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Impetigo | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infection | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laryngitis | | | |
| subjects affected / exposed | 3 / 997 (0.30%) | 3 / 1997 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 6 / 1997 (0.30%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tonsillitis | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower respiratory tract infection viral | | | |

| | | | |
|---|-----------------|-------------------|--|
| subjects affected / exposed | 1 / 997 (0.10%) | 3 / 1997 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pertussis | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pharyngotonsillitis | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia | | | |
| subjects affected / exposed | 5 / 997 (0.50%) | 13 / 1997 (0.65%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia aspiration | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia pneumococcal | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia respiratory syncytial viral | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 2 / 1997 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia viral | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory syncytial virus bronchiolitis | | | |
| subjects affected / exposed | 10 / 997 (1.00%) | 5 / 1997 (0.25%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory syncytial virus bronchitis | | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcal abscess | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcal scalded skin syndrome | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Streptococcal sepsis | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Otitis media | | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 0 / 1997 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urosepsis | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract infection | | | |

| | | | |
|---|-----------------|------------------|--|
| subjects affected / exposed | 5 / 997 (0.50%) | 7 / 1997 (0.35%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 4 / 1997 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tracheobronchitis | | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 0 / 1997 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral infection | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 4 / 1997 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| Dairy intolerance | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Decreased appetite | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dehydration | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Failure to thrive | | | |

| | | | |
|---|-----------------|------------------|--|
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Food refusal | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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

| Non-serious adverse events | Placebo | MEDI8897 | |
|---|--------------------|----------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 836 / 997 (83.85%) | 1717 / 1997 (85.98%) | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Cartilage neoplasm | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Haemangioma | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 9 / 1997 (0.45%) | |
| occurrences (all) | 2 | 9 | |
| Haemangioma of skin | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 2 / 1997 (0.10%) | |
| occurrences (all) | 1 | 2 | |
| Lipoma | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Melanocytic naevus | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 3 / 1997 (0.15%) | |
| occurrences (all) | 0 | 3 | |
| Pyogenic granuloma | | | |

| | | | |
|--|----------------------|-----------------------|--|
| subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 0 / 1997 (0.00%) 0 | |
| Skin papilloma subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 2 / 1997 (0.10%) 2 | |
| Vascular disorders | | | |
| Cyanosis subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 3 / 1997 (0.15%) 3 | |
| Pallor subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 0 / 1997 (0.00%) 0 | |
| Phlebitis subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Surgical and medical procedures | | | |
| Clamping of blood vessel subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Circumcision subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 4 / 1997 (0.20%) 4 | |
| Infection prophylaxis subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Scrotal operation subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Skin lesion removal subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 2 | |
| Urethral repair subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 0 / 1997 (0.00%) 0 | |
| Oral surgery | | | |

| | | | |
|--|----------------------|-----------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Pregnancy, puerperium and perinatal conditions | | | |
| Jaundice neonatal | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Small for dates baby | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Umbilical granuloma | | | |
| subjects affected / exposed | 3 / 997 (0.30%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 3 | 1 | |
| General disorders and administration site conditions | | | |
| Secretion discharge | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) | |
| occurrences (all) | 0 | 2 | |
| Asthenia | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 1 | 1 | |
| Crying | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Developmental delay | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 3 / 1997 (0.15%) | |
| occurrences (all) | 0 | 3 | |
| Discomfort | | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 10 / 1997 (0.50%) | |
| occurrences (all) | 2 | 10 | |
| Fatigue | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Gait disturbance | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Hypothermia | | | |

| | | |
|-----------------------------|--------------------|---------------------|
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Influenza like illness | | |
| subjects affected / exposed | 4 / 997 (0.40%) | 2 / 1997 (0.10%) |
| occurrences (all) | 4 | 2 |
| Injection site induration | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Injection site pain | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 4 / 1997 (0.20%) |
| occurrences (all) | 0 | 4 |
| Injection site swelling | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Malaise | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) |
| occurrences (all) | 0 | 2 |
| Mass | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) |
| occurrences (all) | 0 | 2 |
| PFAPA syndrome | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Pain | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Peripheral swelling | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) |
| occurrences (all) | 0 | 2 |
| Pyrexia | | |
| subjects affected / exposed | 122 / 997 (12.24%) | 290 / 1997 (14.52%) |
| occurrences (all) | 165 | 378 |
| Vaccination site erythema | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) |
| occurrences (all) | 0 | 2 |

| | | | |
|--|------------------------|-------------------------|--|
| Vaccination site reaction subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Vaccination site swelling subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Vessel puncture site haemorrhage subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Xerosis subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 5 / 1997 (0.25%) 6 | |
| Vaccination site pain subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 3 / 1997 (0.15%) 5 | |
| Immune system disorders | | | |
| Allergy to animal subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Allergy to arthropod bite subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 6 / 1997 (0.30%) 6 | |
| Anaphylactic reaction subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 0 / 1997 (0.00%) 0 | |
| Drug hypersensitivity subjects affected / exposed occurrences (all) | 3 / 997 (0.30%) 3 | 9 / 1997 (0.45%) 9 | |
| Dust allergy subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Food allergy subjects affected / exposed occurrences (all) | 18 / 997 (1.81%) 22 | 30 / 1997 (1.50%) 36 | |
| Hypersensitivity | | | |

| | | | |
|--|-----------------|------------------|--|
| subjects affected / exposed | 2 / 997 (0.20%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 2 | 1 | |
| Milk allergy | | | |
| subjects affected / exposed | 4 / 997 (0.40%) | 7 / 1997 (0.35%) | |
| occurrences (all) | 7 | 7 | |
| Multiple allergies | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 2 / 1997 (0.10%) | |
| occurrences (all) | 1 | 2 | |
| Reaction to preservatives | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Seasonal allergy | | | |
| subjects affected / exposed | 6 / 997 (0.60%) | 8 / 1997 (0.40%) | |
| occurrences (all) | 6 | 8 | |
| Reproductive system and breast disorders | | | |
| Genital discomfort | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Acquired hydrocele | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 3 / 1997 (0.15%) | |
| occurrences (all) | 0 | 3 | |
| Balanoposthitis | | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 6 / 1997 (0.30%) | |
| occurrences (all) | 2 | 6 | |
| Breast cyst | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Breast enlargement | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Genital labial adhesions | | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 3 / 1997 (0.15%) | |
| occurrences (all) | 2 | 3 | |
| Genital ulceration | | | |

| | | | |
|--|----------------------|-----------------------|--|
| subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 0 / 1997 (0.00%) 0 | |
| Penile adhesion subjects affected / exposed occurrences (all) | 5 / 997 (0.50%) 5 | 6 / 1997 (0.30%) 6 | |
| Penile discharge subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 0 / 1997 (0.00%) 0 | |
| Penile erythema subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 0 / 1997 (0.00%) 0 | |
| Testicular mass subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 0 / 1997 (0.00%) 0 | |
| Vaginal discharge subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 0 / 1997 (0.00%) 0 | |
| Vulvovaginal adhesion subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 2 / 1997 (0.10%) 2 | |
| Vulvovaginal erythema subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 0 / 1997 (0.00%) 0 | |
| Genital pain subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 0 / 1997 (0.00%) 0 | |
| Respiratory, thoracic and mediastinal disorders Respiratory failure subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Respiration abnormal subjects affected / exposed occurrences (all) | 2 / 997 (0.20%) 2 | 2 / 1997 (0.10%) 2 | |
| Rhinitis allergic | | | |

| | | |
|----------------------------------|------------------|--------------------|
| subjects affected / exposed | 12 / 997 (1.20%) | 13 / 1997 (0.65%) |
| occurrences (all) | 15 | 14 |
| Aphonia | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 2 / 1997 (0.10%) |
| occurrences (all) | 1 | 2 |
| Asthma | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 4 / 1997 (0.20%) |
| occurrences (all) | 1 | 6 |
| Brief resolved unexplained event | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) |
| occurrences (all) | 1 | 1 |
| Bronchial hyperreactivity | | |
| subjects affected / exposed | 3 / 997 (0.30%) | 3 / 1997 (0.15%) |
| occurrences (all) | 3 | 3 |
| Bronchial obstruction | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 4 / 1997 (0.20%) |
| occurrences (all) | 1 | 5 |
| Bronchospasm | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 2 / 1997 (0.10%) |
| occurrences (all) | 1 | 2 |
| Catarrh | | |
| subjects affected / exposed | 8 / 997 (0.80%) | 13 / 1997 (0.65%) |
| occurrences (all) | 12 | 13 |
| Childhood asthma | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Choking | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 2 / 1997 (0.10%) |
| occurrences (all) | 1 | 2 |
| Cough | | |
| subjects affected / exposed | 58 / 997 (5.82%) | 115 / 1997 (5.76%) |
| occurrences (all) | 69 | 145 |
| Dysphonia | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Epistaxis | | |

| | | |
|-----------------------------|------------------|--------------------|
| subjects affected / exposed | 0 / 997 (0.00%) | 4 / 1997 (0.20%) |
| occurrences (all) | 0 | 7 |
| Hiccups | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Nasal congestion | | |
| subjects affected / exposed | 86 / 997 (8.63%) | 164 / 1997 (8.21%) |
| occurrences (all) | 113 | 208 |
| Nasal obstruction | | |
| subjects affected / exposed | 5 / 997 (0.50%) | 18 / 1997 (0.90%) |
| occurrences (all) | 7 | 19 |
| Oropharyngeal pain | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 3 / 1997 (0.15%) |
| occurrences (all) | 2 | 3 |
| Pharyngeal inflammation | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Pneumothorax | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Productive cough | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 1 / 1997 (0.05%) |
| occurrences (all) | 2 | 1 |
| Rhinalgia | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Rhinorrhoea | | |
| subjects affected / exposed | 65 / 997 (6.52%) | 152 / 1997 (7.61%) |
| occurrences (all) | 85 | 216 |
| Sinus congestion | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Sleep apnoea syndrome | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Sneezing | | |

| | | | |
|--------------------------------------|-----------------|-------------------|--|
| subjects affected / exposed | 0 / 997 (0.00%) | 5 / 1997 (0.25%) | |
| occurrences (all) | 0 | 5 | |
| Snoring | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) | |
| occurrences (all) | 0 | 2 | |
| Stridor | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) | |
| occurrences (all) | 0 | 2 | |
| Tachypnoea | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Throat irritation | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Tracheomalacia | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Upper airway obstruction | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) | |
| occurrences (all) | 0 | 2 | |
| Upper respiratory tract congestion | | | |
| subjects affected / exposed | 3 / 997 (0.30%) | 7 / 1997 (0.35%) | |
| occurrences (all) | 3 | 8 | |
| Upper respiratory tract inflammation | | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 6 / 1997 (0.30%) | |
| occurrences (all) | 3 | 11 | |
| Upper respiratory tract irritation | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Vasomotor rhinitis | | | |
| subjects affected / exposed | 5 / 997 (0.50%) | 12 / 1997 (0.60%) | |
| occurrences (all) | 5 | 15 | |
| Wheezing | | | |
| subjects affected / exposed | 4 / 997 (0.40%) | 5 / 1997 (0.25%) | |
| occurrences (all) | 4 | 5 | |
| Psychiatric disorders | | | |

| | | | |
|--|------------------------|-------------------------|--|
| Sleep disorder subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 3 / 1997 (0.15%) 3 | |
| Anxiety subjects affected / exposed occurrences (all) | 2 / 997 (0.20%) 2 | 3 / 1997 (0.15%) 3 | |
| Irritability subjects affected / exposed occurrences (all) | 11 / 997 (1.10%) 11 | 22 / 1997 (1.10%) 26 | |
| Poor quality sleep subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Restlessness subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Hepatobiliary disorders Hyperbilirubinaemia subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Jaundice subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 7 / 1997 (0.35%) 7 | |
| Investigations Alanine aminotransferase increased subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Aspartate aminotransferase increased subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Body temperature increased subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 5 / 1997 (0.25%) 5 | |
| Blood immunoglobulin E increased subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Blood lead increased | | | |

| | | |
|------------------------------|------------------|-------------------|
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Blood copper increased | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Cardiac murmur | | |
| subjects affected / exposed | 4 / 997 (0.40%) | 5 / 1997 (0.25%) |
| occurrences (all) | 4 | 5 |
| Cardiac murmur functional | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Echocardiogram abnormal | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Platelet count increased | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Liver function test abnormal | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) |
| occurrences (all) | 0 | 2 |
| Medical observation normal | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Neutrophil count decreased | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 0 / 1997 (0.00%) |
| occurrences (all) | 2 | 0 |
| Haemoglobin decreased | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| SARS-CoV-2 test negative | | |
| subjects affected / exposed | 27 / 997 (2.71%) | 48 / 1997 (2.40%) |
| occurrences (all) | 30 | 58 |
| SARS-CoV-2 test positive | | |
| subjects affected / exposed | 4 / 997 (0.40%) | 3 / 1997 (0.15%) |
| occurrences (all) | 4 | 3 |
| Transaminases increased | | |

| | | | |
|--|------------------|-------------------|--|
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) | |
| occurrences (all) | 0 | 2 | |
| Urine analysis abnormal | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Injury, poisoning and procedural complications | | | |
| Corneal abrasion | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) | |
| occurrences (all) | 0 | 2 | |
| Animal bite | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Animal scratch | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) | |
| occurrences (all) | 0 | 2 | |
| Arthropod bite | | | |
| subjects affected / exposed | 22 / 997 (2.21%) | 27 / 1997 (1.35%) | |
| occurrences (all) | 24 | 31 | |
| Arthropod sting | | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 2 / 1997 (0.10%) | |
| occurrences (all) | 2 | 2 | |
| Bone contusion | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Brain contusion | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) | |
| occurrences (all) | 0 | 2 | |
| Burns first degree | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 2 / 1997 (0.10%) | |
| occurrences (all) | 1 | 2 | |
| Burns second degree | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 1 | 1 | |
| Chemical burn | | | |

| | | |
|-----------------------------|-----------------|-------------------|
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Concussion | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Contusion | | |
| subjects affected / exposed | 3 / 997 (0.30%) | 11 / 1997 (0.55%) |
| occurrences (all) | 3 | 11 |
| Craniocerebral injury | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 6 / 1997 (0.30%) |
| occurrences (all) | 2 | 6 |
| Post procedural erythema | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Eye contusion | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) |
| occurrences (all) | 1 | 1 |
| Eye injury | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Eyelid injury | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Face injury | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 3 / 1997 (0.15%) |
| occurrences (all) | 2 | 3 |
| Fall | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Femur fracture | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Foreign body in ear | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Foreign body in eye | | |

| | | |
|--|-----------------|-------------------|
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Foreign body in gastrointestinal tract | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) |
| occurrences (all) | 1 | 1 |
| Foreign body in respiratory tract | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Foreign body in throat | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) |
| occurrences (all) | 0 | 2 |
| Foreign body ingestion | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Gingival injury | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 4 / 1997 (0.20%) |
| occurrences (all) | 1 | 4 |
| Hand fracture | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Head injury | | |
| subjects affected / exposed | 6 / 997 (0.60%) | 16 / 1997 (0.80%) |
| occurrences (all) | 7 | 17 |
| Injury | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 2 |
| Limb injury | | |
| subjects affected / exposed | 3 / 997 (0.30%) | 3 / 1997 (0.15%) |
| occurrences (all) | 3 | 3 |
| Lip injury | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) |
| occurrences (all) | 0 | 2 |
| Mouth injury | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) |
| occurrences (all) | 0 | 2 |
| Multiple injuries | | |

| | | |
|-----------------------------|-----------------|------------------|
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Muscle contusion | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Nail injury | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Nasal injury | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) |
| occurrences (all) | 0 | 2 |
| Oral contusion | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Exposure to toxic agent | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Post procedural haemorrhage | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Postoperative ileus | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Procedural pain | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 2 / 1997 (0.10%) |
| occurrences (all) | 1 | 2 |
| Radial head dislocation | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) |
| occurrences (all) | 0 | 2 |
| Road traffic accident | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 3 / 1997 (0.15%) |
| occurrences (all) | 0 | 3 |
| Scratch | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) |
| occurrences (all) | 1 | 1 |
| Skin abrasion | | |

| | | | |
|----------------------------------|------------------|-------------------|--|
| subjects affected / exposed | 3 / 997 (0.30%) | 8 / 1997 (0.40%) | |
| occurrences (all) | 3 | 8 | |
| Skin injury | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) | |
| occurrences (all) | 0 | 2 | |
| Skull fracture | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Thermal burn | | | |
| subjects affected / exposed | 5 / 997 (0.50%) | 10 / 1997 (0.50%) | |
| occurrences (all) | 5 | 11 | |
| Tibia fracture | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Tooth fracture | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Tooth injury | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Traumatic haematoma | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Vaccination complication | | | |
| subjects affected / exposed | 34 / 997 (3.41%) | 72 / 1997 (3.61%) | |
| occurrences (all) | 47 | 90 | |
| Vulvovaginal injury | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Post-traumatic pain | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Congenital, familial and genetic | | | |

| | | | |
|----------------------------------|-----------------|------------------|--|
| disorders | | | |
| Bronchogenic cyst | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Aorta hypoplasia | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Atrial septal defect | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) | |
| occurrences (all) | 0 | 2 | |
| Brachycephaly | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Buried penis syndrome | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Telangiectasia congenital | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Congenital nystagmus | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Congenital tongue anomaly | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Congenital torticollis | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Congenital vesicoureteric reflux | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Cryptorchism | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 2 / 1997 (0.10%) | |
| occurrences (all) | 1 | 2 | |
| Dacryostenosis congenital | | | |

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|---------------------------------|-----------------|-------------------|
| subjects affected / exposed | 3 / 997 (0.30%) | 16 / 1997 (0.80%) |
| occurrences (all) | 3 | 16 |
| Dermoid cyst | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) |
| occurrences (all) | 0 | 2 |
| Developmental hip dysplasia | | |
| subjects affected / exposed | 4 / 997 (0.40%) | 4 / 1997 (0.20%) |
| occurrences (all) | 4 | 4 |
| Hydrocele | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Klippel-Feil syndrome | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Laryngomalacia | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 4 / 1997 (0.20%) |
| occurrences (all) | 0 | 4 |
| Macrocephaly | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 0 / 1997 (0.00%) |
| occurrences (all) | 2 | 0 |
| Mitochondrial encephalomyopathy | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Patent ductus arteriosus | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Phimosis | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 3 / 1997 (0.15%) |
| occurrences (all) | 0 | 3 |
| Plagiocephaly | | |
| subjects affected / exposed | 4 / 997 (0.40%) | 11 / 1997 (0.55%) |
| occurrences (all) | 4 | 11 |
| Talipes | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Congenital anomaly | | |

| | | | |
|--|----------------------|-----------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Vascular malformation subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Ventricular septal defect subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Cardiac disorders | | | |
| Left ventricular hypertrophy subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Supraventricular extrasystoles subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Tachycardia subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Sinus tachycardia subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 0 / 1997 (0.00%) 0 | |
| Nervous system disorders | | | |
| Chorea subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Febrile convulsion subjects affected / exposed occurrences (all) | 5 / 997 (0.50%) 5 | 4 / 1997 (0.20%) 4 | |
| Gross motor delay subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 3 / 1997 (0.15%) 3 | |
| Head discomfort subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Horner's syndrome | | | |

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|-------------------------------|-----------------|------------------|
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Hypertonia | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) |
| occurrences (all) | 1 | 1 |
| Hypotonia | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 1 / 1997 (0.05%) |
| occurrences (all) | 2 | 1 |
| Idiopathic partial epilepsy | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Motor developmental delay | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) |
| occurrences (all) | 0 | 2 |
| Nystagmus | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Post-traumatic epilepsy | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Psychomotor skills impaired | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Seizure | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) |
| occurrences (all) | 0 | 2 |
| Seizure like phenomena | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) |
| occurrences (all) | 1 | 1 |
| Somnolence | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 2 / 1997 (0.10%) |
| occurrences (all) | 1 | 2 |
| Speech disorder developmental | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 3 / 1997 (0.15%) |
| occurrences (all) | 0 | 3 |
| Tremor | | |

| | | | |
|---|----------------------|-------------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 3 / 1997 (0.15%) 3 | |
| Infant irritability subjects affected / exposed occurrences (all) | 4 / 997 (0.40%) 4 | 1 / 1997 (0.05%) 1 | |
| Blood and lymphatic system disorders | | | |
| Lymphadenitis subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 3 / 1997 (0.15%) 3 | |
| Leukocytosis subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Microcytic anaemia subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 2 / 1997 (0.10%) 2 | |
| Neutropenia subjects affected / exposed occurrences (all) | 2 / 997 (0.20%) 2 | 2 / 1997 (0.10%) 2 | |
| Normochromic normocytic anaemia subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 0 / 1997 (0.00%) 0 | |
| Thrombocytopenia subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Thrombocytosis subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 0 / 1997 (0.00%) 0 | |
| Anaemia subjects affected / exposed occurrences (all) | 8 / 997 (0.80%) 8 | 13 / 1997 (0.65%) 13 | |
| Anaemia neonatal subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 3 / 1997 (0.15%) 3 | |
| Hypochromic anaemia subjects affected / exposed occurrences (all) | 7 / 997 (0.70%) 8 | 13 / 1997 (0.65%) 13 | |

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| Iron deficiency anaemia subjects affected / exposed occurrences (all) | 8 / 997 (0.80%) 8 | 14 / 1997 (0.70%) 14 | |
| Lymphadenopathy subjects affected / exposed occurrences (all) | 3 / 997 (0.30%) 3 | 7 / 1997 (0.35%) 7 | |
| Ear and labyrinth disorders | | | |
| Cerumen impaction subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 1 / 1997 (0.05%) 1 | |
| Deafness neurosensory subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 0 / 1997 (0.00%) 0 | |
| Ear pain subjects affected / exposed occurrences (all) | 7 / 997 (0.70%) 8 | 12 / 1997 (0.60%) 14 | |
| Excessive cerumen production subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Middle ear effusion subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 1 / 1997 (0.05%) 1 | |
| Motion sickness subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 2 / 1997 (0.10%) 3 | |
| Otorrhoea subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 1 / 1997 (0.05%) 1 | |
| Tympanic membrane hyperaemia subjects affected / exposed occurrences (all) | 2 / 997 (0.20%) 2 | 0 / 1997 (0.00%) 0 | |
| Eye disorders | | | |
| Eye swelling subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 0 / 1997 (0.00%) 0 | |
| Astigmatism | | | |

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|-----------------------------|-----------------|------------------|
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) |
| occurrences (all) | 1 | 1 |
| Blepharitis | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Cataract subcapsular | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Conjunctival haemorrhage | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Conjunctival hyperaemia | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 0 / 1997 (0.00%) |
| occurrences (all) | 2 | 0 |
| Conjunctivitis allergic | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 6 / 1997 (0.30%) |
| occurrences (all) | 2 | 6 |
| Dacryostenosis acquired | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Erythema of eyelid | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Eye discharge | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 6 / 1997 (0.30%) |
| occurrences (all) | 2 | 6 |
| Pseudostrabismus | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Periorbital oedema | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Pupillary disorder | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Strabismus | | |

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|--|----------------------|-----------------------|--|
| subjects affected / exposed occurrences (all) | 2 / 997 (0.20%) 2 | 3 / 1997 (0.15%) 3 | |
| Swelling of eyelid subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Eyelid oedema subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Hypermetropia subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Keratitis subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 0 / 1997 (0.00%) 0 | |
| Lacrimal structural disorder subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Lacrimation increased subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Ocular hyperaemia subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 4 / 1997 (0.20%) 4 | |
| Pterygium subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Gastrointestinal disorders | | | |
| Abdominal distension subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 5 / 1997 (0.25%) 5 | |
| Abdominal mass subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 0 / 1997 (0.00%) 0 | |
| Abdominal pain subjects affected / exposed occurrences (all) | 3 / 997 (0.30%) 3 | 2 / 1997 (0.10%) 2 | |

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|---|-------------------------|---------------------------|
| Abdominal pain upper subjects affected / exposed occurrences (all) | 2 / 997 (0.20%) 2 | 3 / 1997 (0.15%) 3 |
| Abdominal tenderness subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 |
| Aerophagia subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 |
| Anal fissure subjects affected / exposed occurrences (all) | 3 / 997 (0.30%) 3 | 6 / 1997 (0.30%) 6 |
| Anal polyp subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 0 / 1997 (0.00%) 0 |
| Angular cheilitis subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 |
| Infantile colic subjects affected / exposed occurrences (all) | 11 / 997 (1.10%) 13 | 41 / 1997 (2.05%) 41 |
| Auriculotemporal syndrome subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 0 / 1997 (0.00%) 0 |
| Cheilitis subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 |
| Constipation subjects affected / exposed occurrences (all) | 38 / 997 (3.81%) 42 | 88 / 1997 (4.41%) 96 |
| Diarrhoea subjects affected / exposed occurrences (all) | 89 / 997 (8.93%) 104 | 171 / 1997 (8.56%) 196 |
| Dyspepsia subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 2 / 1997 (0.10%) 2 |

| | | |
|---|------------------|-------------------|
| Enteritis | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 3 / 1997 (0.15%) |
| occurrences (all) | 0 | 3 |
| Enterocolitis | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Epulis | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Faecaloma | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Faeces discoloured | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 1 / 1997 (0.05%) |
| occurrences (all) | 2 | 1 |
| Faeces soft | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 3 / 1997 (0.15%) |
| occurrences (all) | 2 | 3 |
| Flatulence | | |
| subjects affected / exposed | 4 / 997 (0.40%) | 13 / 1997 (0.65%) |
| occurrences (all) | 4 | 13 |
| Food protein-induced enterocolitis syndrome | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Gastritis | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) |
| occurrences (all) | 1 | 1 |
| Gastritis erosive | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Gastrooesophageal reflux disease | | |
| subjects affected / exposed | 14 / 997 (1.40%) | 31 / 1997 (1.55%) |
| occurrences (all) | 14 | 32 |
| Gingival cyst | | |

| | | |
|-----------------------------|------------------|-------------------|
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Gingival discomfort | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Gingival pain | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 3 | 0 |
| Haematemesis | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 3 / 1997 (0.15%) |
| occurrences (all) | 0 | 3 |
| Haematochezia | | |
| subjects affected / exposed | 5 / 997 (0.50%) | 2 / 1997 (0.10%) |
| occurrences (all) | 6 | 2 |
| Infant dyschezia | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Aphthous ulcer | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 2 / 1997 (0.10%) |
| occurrences (all) | 2 | 2 |
| Vomiting | | |
| subjects affected / exposed | 32 / 997 (3.21%) | 59 / 1997 (2.95%) |
| occurrences (all) | 35 | 63 |
| Umbilical hernia | | |
| subjects affected / exposed | 4 / 997 (0.40%) | 14 / 1997 (0.70%) |
| occurrences (all) | 4 | 14 |
| Infantile spitting up | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Inguinal hernia | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) |
| occurrences (all) | 1 | 1 |
| Lip ulceration | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Melaena | | |

| | | | |
|--|------------------|--------------------|--|
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Mouth ulceration | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) | |
| occurrences (all) | 0 | 2 | |
| Mucous stools | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Oesophageal perforation | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Oral mucosal eruption | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Regurgitation | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) | |
| occurrences (all) | 0 | 2 | |
| Stomatitis | | | |
| subjects affected / exposed | 4 / 997 (0.40%) | 7 / 1997 (0.35%) | |
| occurrences (all) | 4 | 7 | |
| Teething | | | |
| subjects affected / exposed | 70 / 997 (7.02%) | 138 / 1997 (6.91%) | |
| occurrences (all) | 85 | 171 | |
| Toothache | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 6 / 1997 (0.30%) | |
| occurrences (all) | 1 | 12 | |
| Skin and subcutaneous tissue disorders | | | |
| Acne infantile | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 4 / 1997 (0.20%) | |
| occurrences (all) | 1 | 4 | |
| Asteatosis | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 4 / 1997 (0.20%) | |
| occurrences (all) | 0 | 4 | |
| Blister | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 1 | 1 | |

| | | |
|-----------------------------|--------------------|---------------------|
| Cafe au lait spots | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) |
| occurrences (all) | 1 | 1 |
| Dandruff | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Dermatitis | | |
| subjects affected / exposed | 21 / 997 (2.11%) | 44 / 1997 (2.20%) |
| occurrences (all) | 22 | 44 |
| Dermatitis allergic | | |
| subjects affected / exposed | 5 / 997 (0.50%) | 11 / 1997 (0.55%) |
| occurrences (all) | 5 | 12 |
| Dermatitis atopic | | |
| subjects affected / exposed | 25 / 997 (2.51%) | 56 / 1997 (2.80%) |
| occurrences (all) | 28 | 59 |
| Dermatitis contact | | |
| subjects affected / exposed | 16 / 997 (1.60%) | 39 / 1997 (1.95%) |
| occurrences (all) | 18 | 41 |
| Dermatitis diaper | | |
| subjects affected / exposed | 103 / 997 (10.33%) | 224 / 1997 (11.22%) |
| occurrences (all) | 118 | 267 |
| Petechiae | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Drug eruption | | |
| subjects affected / exposed | 3 / 997 (0.30%) | 4 / 1997 (0.20%) |
| occurrences (all) | 3 | 4 |
| Dry skin | | |
| subjects affected / exposed | 19 / 997 (1.91%) | 39 / 1997 (1.95%) |
| occurrences (all) | 19 | 41 |
| Dyshidrotic eczema | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) |
| occurrences (all) | 0 | 2 |
| Eczema | | |

| | | |
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| subjects affected / exposed | 52 / 997 (5.22%) | 90 / 1997 (4.51%) |
| occurrences (all) | 59 | 98 |
| Eczema asteatotic | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 6 / 1997 (0.30%) |
| occurrences (all) | 1 | 6 |
| Eczema infantile | | |
| subjects affected / exposed | 9 / 997 (0.90%) | 21 / 1997 (1.05%) |
| occurrences (all) | 11 | 23 |
| Eczema nummular | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) |
| occurrences (all) | 0 | 2 |
| Ephelides | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Erythema | | |
| subjects affected / exposed | 4 / 997 (0.40%) | 3 / 1997 (0.15%) |
| occurrences (all) | 4 | 3 |
| Erythema toxicum neonatorum | | |
| subjects affected / exposed | 3 / 997 (0.30%) | 5 / 1997 (0.25%) |
| occurrences (all) | 3 | 5 |
| Haemorrhage subcutaneous | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Hand dermatitis | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Idiopathic urticaria | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Ingrowing nail | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) |
| occurrences (all) | 1 | 1 |
| Intertrigo | | |
| subjects affected / exposed | 4 / 997 (0.40%) | 2 / 1997 (0.10%) |
| occurrences (all) | 4 | 2 |
| Keratosis pilaris | | |

| | | |
|---------------------------------------|------------------|-------------------|
| subjects affected / exposed | 2 / 997 (0.20%) | 5 / 1997 (0.25%) |
| occurrences (all) | 2 | 5 |
| Lichen striatus | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Macule | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Miliaria | | |
| subjects affected / exposed | 37 / 997 (3.71%) | 60 / 1997 (3.00%) |
| occurrences (all) | 47 | 71 |
| Nail discolouration | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Neurodermatitis | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 2 / 1997 (0.10%) |
| occurrences (all) | 1 | 2 |
| Papule | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 2 / 1997 (0.10%) |
| occurrences (all) | 2 | 2 |
| Perioral dermatitis | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 0 / 1997 (0.00%) |
| occurrences (all) | 2 | 0 |
| Dermatosis | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Pityriasis rosea | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Post inflammatory pigmentation change | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) |
| occurrences (all) | 0 | 2 |
| Prurigo | | |
| subjects affected / exposed | 3 / 997 (0.30%) | 6 / 1997 (0.30%) |
| occurrences (all) | 3 | 6 |

| | | |
|-----------------------------|------------------|-------------------|
| Rash | | |
| subjects affected / exposed | 48 / 997 (4.81%) | 93 / 1997 (4.66%) |
| occurrences (all) | 55 | 108 |
| Rash erythematous | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 3 / 1997 (0.15%) |
| occurrences (all) | 1 | 3 |
| Rash macular | | |
| subjects affected / exposed | 3 / 997 (0.30%) | 2 / 1997 (0.10%) |
| occurrences (all) | 3 | 2 |
| Rash maculo-papular | | |
| subjects affected / exposed | 8 / 997 (0.80%) | 17 / 1997 (0.85%) |
| occurrences (all) | 8 | 17 |
| Rash papular | | |
| subjects affected / exposed | 8 / 997 (0.80%) | 15 / 1997 (0.75%) |
| occurrences (all) | 8 | 15 |
| Rash pruritic | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Seborrhoea | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 3 / 1997 (0.15%) |
| occurrences (all) | 1 | 3 |
| Seborrhoeic dermatitis | | |
| subjects affected / exposed | 17 / 997 (1.71%) | 40 / 1997 (2.00%) |
| occurrences (all) | 17 | 40 |
| Skin exfoliation | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 2 / 1997 (0.10%) |
| occurrences (all) | 1 | 2 |
| Skin hypopigmentation | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 6 / 1997 (0.30%) |
| occurrences (all) | 2 | 6 |
| Skin irritation | | |
| subjects affected / exposed | 3 / 997 (0.30%) | 15 / 1997 (0.75%) |
| occurrences (all) | 3 | 18 |
| Thermal burn | | |
| subjects affected / exposed | 5 / 997 (0.50%) | 10 / 1997 (0.50%) |
| occurrences (all) | 5 | 11 |

| | | | |
|---|-----------------------|-------------------------|--|
| Toxic skin eruption subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Transient neonatal pustular melanosis subjects affected / exposed occurrences (all) | 2 / 997 (0.20%) 2 | 0 / 1997 (0.00%) 0 | |
| Urticaria subjects affected / exposed occurrences (all) | 9 / 997 (0.90%) 11 | 21 / 1997 (1.05%) 25 | |
| Urticaria chronic subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Urticaria contact subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 2 | 0 / 1997 (0.00%) 0 | |
| Xeroderma subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 0 / 1997 (0.00%) 0 | |
| Pityriasis alba subjects affected / exposed occurrences (all) | 4 / 997 (0.40%) 4 | 10 / 1997 (0.50%) 10 | |
| Renal and urinary disorders Haematuria subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Vesicoureteric reflux subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Dysuria subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all) | 2 / 997 (0.20%) 2 | 0 / 1997 (0.00%) 0 | |
| Musculoskeletal and connective tissue disorders | | | |

| | | |
|-----------------------------|-----------------|------------------|
| Foot deformity | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Diastasis recti abdominis | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Acquired plagiocephaly | | |
| subjects affected / exposed | 3 / 997 (0.30%) | 3 / 1997 (0.15%) |
| occurrences (all) | 3 | 3 |
| Arthropathy | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Growth retardation | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) |
| occurrences (all) | 1 | 1 |
| Head deformity | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Limb discomfort | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Musculoskeletal pain | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Posture abnormal | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Rib deformity | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Scoliosis | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Torticollis | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 3 / 1997 (0.15%) |
| occurrences (all) | 1 | 3 |

| | | | |
|--|----------------------|-----------------------|--|
| Haematoma muscle subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 | |
| Infections and infestations | | | |
| Abscess | | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 2 / 1997 (0.10%) | |
| occurrences (all) | 2 | 2 | |
| Abscess jaw | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Abscess limb | | | |
| subjects affected / exposed | 3 / 997 (0.30%) | 2 / 1997 (0.10%) | |
| occurrences (all) | 3 | 2 | |
| Abscess neck | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 1 | 1 | |
| Acarodermatitis | | | |
| subjects affected / exposed | 15 / 997 (1.50%) | 32 / 1997 (1.60%) | |
| occurrences (all) | 20 | 39 | |
| Acute sinusitis | | | |
| subjects affected / exposed | 3 / 997 (0.30%) | 2 / 1997 (0.10%) | |
| occurrences (all) | 3 | 2 | |
| Adenoviral upper respiratory infection | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 6 / 1997 (0.30%) | |
| occurrences (all) | 0 | 6 | |
| Adenovirus infection | | | |
| subjects affected / exposed | 3 / 997 (0.30%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 3 | 1 | |
| Amoebiasis | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 3 / 1997 (0.15%) | |
| occurrences (all) | 0 | 3 | |
| Amoebic dysentery | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) | |
| occurrences (all) | 0 | 2 | |
| Anal abscess | | | |

| | | |
|-----------------------------|------------------|--------------------|
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Ascariasis | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Asymptomatic COVID-19 | | |
| subjects affected / exposed | 7 / 997 (0.70%) | 8 / 1997 (0.40%) |
| occurrences (all) | 8 | 8 |
| Bacterial disease carrier | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Body tinea | | |
| subjects affected / exposed | 12 / 997 (1.20%) | 20 / 1997 (1.00%) |
| occurrences (all) | 14 | 22 |
| Borrelia infection | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Bronchiolitis | | |
| subjects affected / exposed | 71 / 997 (7.12%) | 119 / 1997 (5.96%) |
| occurrences (all) | 86 | 139 |
| Bronchitis | | |
| subjects affected / exposed | 31 / 997 (3.11%) | 60 / 1997 (3.00%) |
| occurrences (all) | 34 | 76 |
| Bronchitis viral | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 1 / 1997 (0.05%) |
| occurrences (all) | 3 | 1 |
| Bullous impetigo | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 5 / 1997 (0.25%) |
| occurrences (all) | 1 | 5 |
| COVID-19 | | |
| subjects affected / exposed | 59 / 997 (5.92%) | 97 / 1997 (4.86%) |
| occurrences (all) | 62 | 98 |
| Candida infection | | |
| subjects affected / exposed | 5 / 997 (0.50%) | 4 / 1997 (0.20%) |
| occurrences (all) | 5 | 5 |
| Candida nappy rash | | |

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|-----------------------------|------------------|--------------------|
| subjects affected / exposed | 3 / 997 (0.30%) | 19 / 1997 (0.95%) |
| occurrences (all) | 3 | 19 |
| Cellulitis | | |
| subjects affected / exposed | 3 / 997 (0.30%) | 6 / 1997 (0.30%) |
| occurrences (all) | 3 | 6 |
| Citrobacter infection | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Conjunctivitis | | |
| subjects affected / exposed | 56 / 997 (5.62%) | 137 / 1997 (6.86%) |
| occurrences (all) | 61 | 157 |
| Conjunctivitis bacterial | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 6 / 1997 (0.30%) |
| occurrences (all) | 3 | 6 |
| Conjunctivitis viral | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 3 / 1997 (0.15%) |
| occurrences (all) | 0 | 3 |
| Croup infectious | | |
| subjects affected / exposed | 7 / 997 (0.70%) | 17 / 1997 (0.85%) |
| occurrences (all) | 7 | 18 |
| Gastroenteritis viral | | |
| subjects affected / exposed | 8 / 997 (0.80%) | 21 / 1997 (1.05%) |
| occurrences (all) | 11 | 23 |
| Dacryocanaliculitis | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) |
| occurrences (all) | 0 | 2 |
| Dacryocystitis | | |
| subjects affected / exposed | 3 / 997 (0.30%) | 2 / 1997 (0.10%) |
| occurrences (all) | 3 | 2 |
| Dermatitis infected | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) |
| occurrences (all) | 1 | 1 |
| Dermatophytosis | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Diarrhoea infectious | | |

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|-----------------------------|------------------|-------------------|
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Dysentery | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 1 / 1997 (0.05%) |
| occurrences (all) | 2 | 1 |
| Ear infection | | |
| subjects affected / exposed | 4 / 997 (0.40%) | 4 / 1997 (0.20%) |
| occurrences (all) | 5 | 4 |
| Ear infection bacterial | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Ear lobe infection | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Eczema infected | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 2 / 1997 (0.10%) |
| occurrences (all) | 1 | 2 |
| Enterobiasis | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Enterovirus infection | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 4 / 1997 (0.20%) |
| occurrences (all) | 1 | 5 |
| Exanthema subitum | | |
| subjects affected / exposed | 27 / 997 (2.71%) | 30 / 1997 (1.50%) |
| occurrences (all) | 27 | 30 |
| Eye infection | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 7 / 1997 (0.35%) |
| occurrences (all) | 1 | 9 |
| Febrile infection | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 2 / 1997 (0.10%) |
| occurrences (all) | 1 | 2 |
| Folliculitis | | |
| subjects affected / exposed | 4 / 997 (0.40%) | 14 / 1997 (0.70%) |
| occurrences (all) | 4 | 15 |
| Fungal infection | | |

| | | |
|-----------------------------|--------------------|---------------------|
| subjects affected / exposed | 1 / 997 (0.10%) | 2 / 1997 (0.10%) |
| occurrences (all) | 1 | 2 |
| Fungal skin infection | | |
| subjects affected / exposed | 19 / 997 (1.91%) | 35 / 1997 (1.75%) |
| occurrences (all) | 19 | 37 |
| Furuncle | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 3 / 1997 (0.15%) |
| occurrences (all) | 1 | 3 |
| Gastroenteritis | | |
| subjects affected / exposed | 100 / 997 (10.03%) | 202 / 1997 (10.12%) |
| occurrences (all) | 113 | 246 |
| Gastroenteritis adenovirus | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) |
| occurrences (all) | 0 | 2 |
| Gastroenteritis bacterial | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) |
| occurrences (all) | 0 | 2 |
| Gastroenteritis enteroviral | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Gastroenteritis rotavirus | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Cystitis | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Joint abscess | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Influenza | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 9 / 1997 (0.45%) |
| occurrences (all) | 1 | 10 |
| Lice infestation | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |

| | | |
|---|------------------------|-------------------------|
| Lower respiratory tract infection subjects affected / exposed occurrences (all) | 34 / 997 (3.41%) 44 | 47 / 1997 (2.35%) 69 |
| Lower respiratory tract infection viral subjects affected / exposed occurrences (all) | 12 / 997 (1.20%) 12 | 9 / 1997 (0.45%) 9 |
| Lyme disease subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 |
| Measles subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 |
| Mediastinitis subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 |
| Meningitis aseptic subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 0 / 1997 (0.00%) 0 |
| Metapneumovirus infection subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 |
| Gastrointestinal infection subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 1 / 1997 (0.05%) 2 |
| Gastrointestinal viral infection subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 3 / 1997 (0.15%) 3 |
| Genital candidiasis subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 2 / 1997 (0.10%) 2 |
| Genital infection fungal subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 0 / 1997 (0.00%) 0 |
| Gianotti-Crosti syndrome subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 |

| | | |
|---|------------------------|-------------------------|
| Hand-foot-and-mouth disease subjects affected / exposed occurrences (all) | 19 / 997 (1.91%) 19 | 42 / 1997 (2.10%) 43 |
| Helminthic infection subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 0 / 1997 (0.00%) 0 |
| Herpangina subjects affected / exposed occurrences (all) | 3 / 997 (0.30%) 3 | 5 / 1997 (0.25%) 5 |
| Herpes ophthalmic subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 |
| Hordeolum subjects affected / exposed occurrences (all) | 2 / 997 (0.20%) 2 | 5 / 1997 (0.25%) 5 |
| Human herpesvirus 6 infection subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 |
| Impetigo subjects affected / exposed occurrences (all) | 31 / 997 (3.11%) 35 | 43 / 1997 (2.15%) 47 |
| Infected bite subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 |
| Infected dermal cyst subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 0 / 1997 (0.00%) 0 |
| Infected skin ulcer subjects affected / exposed occurrences (all) | 0 / 997 (0.00%) 0 | 1 / 1997 (0.05%) 1 |
| Infection subjects affected / exposed occurrences (all) | 1 / 997 (0.10%) 1 | 0 / 1997 (0.00%) 0 |
| Laryngitis subjects affected / exposed occurrences (all) | 9 / 997 (0.90%) 9 | 35 / 1997 (1.75%) 37 |

| | | |
|-----------------------------|------------------|--------------------|
| Molluscum contagiosum | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 9 / 1997 (0.45%) |
| occurrences (all) | 1 | 10 |
| Pyoderma streptococcal | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Omphalitis | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) |
| occurrences (all) | 0 | 2 |
| Oral candidiasis | | |
| subjects affected / exposed | 22 / 997 (2.21%) | 55 / 1997 (2.75%) |
| occurrences (all) | 23 | 60 |
| Oral fungal infection | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Oral herpes | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 4 / 1997 (0.20%) |
| occurrences (all) | 1 | 4 |
| Oral infection | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Otitis externa | | |
| subjects affected / exposed | 6 / 997 (0.60%) | 6 / 1997 (0.30%) |
| occurrences (all) | 6 | 6 |
| Otitis media | | |
| subjects affected / exposed | 76 / 997 (7.62%) | 154 / 1997 (7.71%) |
| occurrences (all) | 111 | 218 |
| Otitis media acute | | |
| subjects affected / exposed | 44 / 997 (4.41%) | 82 / 1997 (4.11%) |
| occurrences (all) | 53 | 126 |
| Otitis media chronic | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 2 / 1997 (0.10%) |
| occurrences (all) | 2 | 2 |
| Parasitic gastroenteritis | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 4 / 1997 (0.20%) |
| occurrences (all) | 2 | 4 |

| | | |
|-----------------------------|------------------|-------------------|
| Paronychia | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 11 / 1997 (0.55%) |
| occurrences (all) | 2 | 12 |
| Periorbital cellulitis | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) |
| occurrences (all) | 0 | 2 |
| Pertussis | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Pharyngitis | | |
| subjects affected / exposed | 28 / 997 (2.81%) | 72 / 1997 (3.61%) |
| occurrences (all) | 28 | 80 |
| Pharyngitis streptococcal | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) |
| occurrences (all) | 0 | 2 |
| Pharyngotonsillitis | | |
| subjects affected / exposed | 9 / 997 (0.90%) | 16 / 1997 (0.80%) |
| occurrences (all) | 9 | 16 |
| Pneumonia | | |
| subjects affected / exposed | 6 / 997 (0.60%) | 11 / 1997 (0.55%) |
| occurrences (all) | 6 | 11 |
| Pneumonia bacterial | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) |
| occurrences (all) | 0 | 2 |
| Pneumonia moraxella | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Pulmonary tuberculosis | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) |
| occurrences (all) | 1 | 1 |
| Pustule | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 2 / 1997 (0.10%) |
| occurrences (all) | 1 | 2 |
| Pyelonephritis | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |

| | | | |
|--|--------------------|---------------------|--|
| Pyoderma | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 3 / 1997 (0.15%) | |
| occurrences (all) | 1 | 3 | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 237 / 997 (23.77%) | 441 / 1997 (22.08%) | |
| occurrences (all) | 471 | 946 | |
| Rash pustular | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) | |
| occurrences (all) | 0 | 2 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 316 / 997 (31.70%) | 639 / 1997 (32.00%) | |
| occurrences (all) | 621 | 1316 | |
| Respiratory syncytial virus bronchitis | | | |
| subjects affected / exposed | 3 / 997 (0.30%) | 0 / 1997 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Rhinitis | | | |
| subjects affected / exposed | 102 / 997 (10.23%) | 201 / 1997 (10.07%) | |
| occurrences (all) | 146 | 272 | |
| Rhinolaryngitis | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Roseola | | | |
| subjects affected / exposed | 14 / 997 (1.40%) | 24 / 1997 (1.20%) | |
| occurrences (all) | 14 | 24 | |
| Scarlet fever | | | |

| | | |
|-----------------------------|-----------------|-------------------|
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Sinusitis | | |
| subjects affected / exposed | 7 / 997 (0.70%) | 9 / 1997 (0.45%) |
| occurrences (all) | 7 | 9 |
| Sinusitis bacterial | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) |
| occurrences (all) | 1 | 1 |
| Skin bacterial infection | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) |
| occurrences (all) | 0 | 2 |
| Skin candida | | |
| subjects affected / exposed | 3 / 997 (0.30%) | 9 / 1997 (0.45%) |
| occurrences (all) | 3 | 9 |
| Skin infection | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 2 / 1997 (0.10%) |
| occurrences (all) | 3 | 2 |
| Subcutaneous abscess | | |
| subjects affected / exposed | 3 / 997 (0.30%) | 2 / 1997 (0.10%) |
| occurrences (all) | 3 | 2 |
| Subglottic laryngitis | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 1 / 1997 (0.05%) |
| occurrences (all) | 3 | 1 |
| Suspected COVID-19 | | |
| subjects affected / exposed | 7 / 997 (0.70%) | 10 / 1997 (0.50%) |
| occurrences (all) | 7 | 10 |
| Tinea capitis | | |
| subjects affected / exposed | 3 / 997 (0.30%) | 1 / 1997 (0.05%) |
| occurrences (all) | 3 | 1 |
| Tinea cruris | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) |
| occurrences (all) | 1 | 0 |
| Tinea infection | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 4 / 1997 (0.20%) |
| occurrences (all) | 0 | 4 |
| Tinea pedis | | |

| | | |
|--|------------------|-------------------|
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) |
| occurrences (all) | 1 | 1 |
| Tinea versicolour | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) |
| occurrences (all) | 1 | 1 |
| Tonsillitis | | |
| subjects affected / exposed | 7 / 997 (0.70%) | 14 / 1997 (0.70%) |
| occurrences (all) | 7 | 15 |
| Tracheitis | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 4 / 1997 (0.20%) |
| occurrences (all) | 2 | 4 |
| Tracheobronchitis | | |
| subjects affected / exposed | 3 / 997 (0.30%) | 2 / 1997 (0.10%) |
| occurrences (all) | 3 | 2 |
| Respiratory syncytial virus bronchiolitis | | |
| subjects affected / exposed | 14 / 997 (1.40%) | 13 / 1997 (0.65%) |
| occurrences (all) | 14 | 13 |
| Urinary tract infection | | |
| subjects affected / exposed | 14 / 997 (1.40%) | 22 / 1997 (1.10%) |
| occurrences (all) | 15 | 26 |
| Vaccination site infection | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Varicella | | |
| subjects affected / exposed | 10 / 997 (1.00%) | 22 / 1997 (1.10%) |
| occurrences (all) | 10 | 22 |
| Varicella zoster virus infection | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 2 / 1997 (0.10%) |
| occurrences (all) | 1 | 2 |
| Viral diarrhoea | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) |
| occurrences (all) | 1 | 1 |
| Viral infection | | |
| subjects affected / exposed | 21 / 997 (2.11%) | 35 / 1997 (1.75%) |
| occurrences (all) | 22 | 36 |

| | | | |
|---|------------------|--------------------|--|
| Viral pharyngitis | | | |
| subjects affected / exposed | 2 / 997 (0.20%) | 9 / 1997 (0.45%) | |
| occurrences (all) | 2 | 9 | |
| Viral rash | | | |
| subjects affected / exposed | 30 / 997 (3.01%) | 85 / 1997 (4.26%) | |
| occurrences (all) | 32 | 90 | |
| Viral rhinitis | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Viral tonsillitis | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 2 / 1997 (0.10%) | |
| occurrences (all) | 1 | 2 | |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 60 / 997 (6.02%) | 132 / 1997 (6.61%) | |
| occurrences (all) | 77 | 162 | |
| Wound infection | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 0 / 1997 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Urinary tract infection bacterial | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Metabolism and nutrition disorders | | | |
| Abnormal weight gain | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Breast milk substitute intolerance | | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Dairy intolerance | | | |
| subjects affected / exposed | 3 / 997 (0.30%) | 4 / 1997 (0.20%) | |
| occurrences (all) | 3 | 4 | |
| Decreased appetite | | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 2 / 1997 (0.10%) | |
| occurrences (all) | 1 | 2 | |
| Dehydration | | | |

| | | |
|-----------------------------|-----------------|------------------|
| subjects affected / exposed | 5 / 997 (0.50%) | 2 / 1997 (0.10%) |
| occurrences (all) | 5 | 2 |
| Failure to thrive | | |
| subjects affected / exposed | 3 / 997 (0.30%) | 6 / 1997 (0.30%) |
| occurrences (all) | 3 | 6 |
| Hyperglycaemia | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Hypoglycaemia | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) |
| occurrences (all) | 0 | 2 |
| Iron deficiency | | |
| subjects affected / exposed | 1 / 997 (0.10%) | 1 / 1997 (0.05%) |
| occurrences (all) | 1 | 1 |
| Lactose intolerance | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 4 / 1997 (0.20%) |
| occurrences (all) | 0 | 4 |
| Malnutrition | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 5 / 1997 (0.25%) |
| occurrences (all) | 0 | 5 |
| Poor feeding infant | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Underweight | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 2 / 1997 (0.10%) |
| occurrences (all) | 0 | 2 |
| Vitamin B12 deficiency | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Vitamin D deficiency | | |
| subjects affected / exposed | 0 / 997 (0.00%) | 1 / 1997 (0.05%) |
| occurrences (all) | 0 | 1 |
| Weight gain poor | | |
| subjects affected / exposed | 5 / 997 (0.50%) | 7 / 1997 (0.35%) |
| occurrences (all) | 5 | 7 |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|------------------|--|
| 01 February 2021 | The MELODY study was amended to mitigate for the greatly reduced circulation of RSV due to measures associated with the pandemic and the challenges of operating a trial during the pandemic. In agreement with the FDA at a Type B meeting (02 December 2020) discussing the impact of COVID-19 on the registrational studies/clinical package for the BLA, the MELODY Primary Analysis would be conducted based on the 1490 subjects randomised prior to the pause in enrolment with completion of the full sample size in a complementary Safety Cohort |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

| Date | Interruption | Restart date |
|--------------|--|---------------|
| 02 July 2020 | study enrolment was paused due to the impact of the COVID-19 pandemic. | 09 April 2021 |

Notes:

Limitations and caveats

None reported