



Clinical trial results:

A Phase III, randomized, double-blind, placebo controlled multi-country study to demonstrate efficacy of a single dose of unadjuvanted RSV Maternal vaccine, administered IM to pregnant women 18 to 49 years of age, for prevention of RSV associated LRTI in their infants up to 6 months of age

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2020-001355-40 |
| Trial protocol | FI FR BE IT ES |
| Global end of trial date | 14 June 2023 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 |
| This version publication date | 05 July 2024 |
| First version publication date | 05 July 2024 |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | 212171 |
|-----------------------|--------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT04605159 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | GlaxoSmithKline |
| Sponsor organisation address | Rue de l'Institut 89, Rixensart, Belgium, B-1330 |
| Public contact | GSK Response Center, GlaxoSmithKline, 44 8664357343, GSKClinicalSupportHD@gsk.com |
| Scientific contact | GSK Response Center, GlaxoSmithKline, 44 8664357343, GSKClinicalSupportHD@gsk.com |

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

| | |
|--|-----------------|
| Analysis stage | Final |
| Date of interim/final analysis | 20 October 2023 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 14 June 2023 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

- To assess the efficacy of a single dose of the RSV Maternal vaccine administered to maternal participants in preventing medically assessed, RSV-associated severe LRTIs in their infant participants up to 6 months of age.
- To assess the efficacy of a single dose of the RSV Maternal vaccine administered to maternal participants in preventing medically assessed, RSV-associated LRTIs of any severity in their infant participants up to 6 months of age.
- To evaluate the safety of the RSV Maternal vaccine in infants born to mothers who were vaccinated with a single intramuscular (IM) dose of study vaccine, up to 12 months after birth.

Protection of trial subjects:

All maternal participants were observed closely for at least 30 minutes after the administration of the vaccine/product. Appropriate medical treatment was readily available during the observation period in case of anaphylaxis and/or syncope. Vaccines/products were administered by qualified and trained personnel. Vaccines/products were administered only to eligible participants that had no contraindications to any components of the vaccines/products.

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 20 November 2020 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|------------------------|
| Country: Number of subjects enrolled | Argentina: 566 |
| Country: Number of subjects enrolled | Australia: 83 |
| Country: Number of subjects enrolled | Bangladesh: 642 |
| Country: Number of subjects enrolled | Belgium: 118 |
| Country: Number of subjects enrolled | Brazil: 155 |
| Country: Number of subjects enrolled | Canada: 92 |
| Country: Number of subjects enrolled | Colombia: 541 |
| Country: Number of subjects enrolled | Dominican Republic: 59 |
| Country: Number of subjects enrolled | Finland: 389 |
| Country: Number of subjects enrolled | France: 68 |
| Country: Number of subjects enrolled | Honduras: 60 |
| Country: Number of subjects enrolled | India: 119 |
| Country: Number of subjects enrolled | Italy: 128 |
| Country: Number of subjects enrolled | Korea, Republic of: 28 |

| | |
|--------------------------------------|---------------------|
| Country: Number of subjects enrolled | Mexico: 88 |
| Country: Number of subjects enrolled | New Zealand: 434 |
| Country: Number of subjects enrolled | Panama: 1471 |
| Country: Number of subjects enrolled | Philippines: 695 |
| Country: Number of subjects enrolled | South Africa: 1307 |
| Country: Number of subjects enrolled | Spain: 1526 |
| Country: Number of subjects enrolled | Taiwan: 229 |
| Country: Number of subjects enrolled | Thailand: 114 |
| Country: Number of subjects enrolled | United Kingdom: 2 |
| Country: Number of subjects enrolled | United States: 2280 |
| Worldwide total number of subjects | 11194 |
| EEA total number of subjects | 2229 |

Notes:

Subjects enrolled per age group

| | |
|---|------|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 323 |
| Newborns (0-27 days) | 4912 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 5959 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 11194 participants (5959 maternal participants and 5235 infants) completed the informed consent process, of which 5328 maternal participants were exposed to the study intervention, and 5235 infants were born to those exposed mothers (RSV MAT Group - Mother and Placebo Group - Mother). Therefore, 10563 participants started the study.

Period 1

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

Blinding implementation details:

The study was conducted in a double-blinded manner, but the study was unblinded following the decision to stop enrollment and vaccination in the study due to a safety signal.

Arms

| | |
|------------------------------|------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | RSV MAT Group - Mother |

Arm description:

Maternal participants received a single dose of the RSV MAT vaccine administered at Day 1 in this study.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | RSV MAT |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder and solution for solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Single dose of the RSV MAT vaccine reconstituted with NaCl solution, administered intramuscularly in the non-dominant arm, at Day 1.

| | |
|------------------|------------------------|
| Arm title | Placebo Group - Mother |
|------------------|------------------------|

Arm description:

Maternal participants received a single dose of placebo administered at Day 1 in this study.

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

Dosage and administration details:

Single dose of Placebo (lyophilized sucrose reconstituted with NaCl solution), administered intramuscularly in the non-dominant arm, at Day 1.

| | |
|------------------|------------------------|
| Arm title | RSV MAT Group - Infant |
|------------------|------------------------|

Arm description:

This group consisted of infants born to mothers (from RSV MAT Group - Mother) who received a single dose of RSV MAT vaccine during pregnancy.

| | |
|---|-----------------|
| Arm type | No intervention |
| No investigational medicinal product assigned in this arm | |

| | |
|---|------------------------|
| Arm title | Placebo Group - Infant |
| Arm description: This group consisted of infants born to mothers (from Placebo Group - Mother) who received a single dose of placebo during pregnancy. | |
| Arm type | No intervention |
| No investigational medicinal product assigned in this arm | |

| Number of subjects in period 1^[1] | RSV MAT Group - Mother | Placebo Group - Mother | RSV MAT Group - Infant |
|---|------------------------|------------------------|------------------------|
| Started | 3557 | 1771 | 3494 |
| Completed | 3374 | 1657 | 3236 |
| Not completed | 183 | 114 | 258 |
| Consent withdrawn by subject | 66 | 37 | 68 |
| Adverse event, non-fatal | 6 | 3 | 21 |
| Migrated / moved from the study area | 32 | 22 | 41 |
| Unspecified | 1 | 2 | 7 |
| Lost to follow-up | 74 | 45 | 119 |
| Protocol deviation | 4 | 5 | 2 |

| Number of subjects in period 1^[1] | Placebo Group - Infant |
|---|------------------------|
| Started | 1741 |
| Completed | 1583 |
| Not completed | 158 |
| Consent withdrawn by subject | 50 |
| Adverse event, non-fatal | 4 |
| Migrated / moved from the study area | 21 |
| Unspecified | 3 |
| Lost to follow-up | 80 |
| Protocol deviation | - |

Notes:

[1] - 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: A total of 11194 participants (5959 maternal participants and 5235 infants) completed the informed consent process, of which 5328 maternal participants were exposed to the study intervention, and 5235 infants were born to those exposed mothers (RSV MAT Group - Mother and Placebo Group - Mother). Therefore, 10563 participants started the study.

Baseline characteristics

Reporting groups

| | |
|---|------------------------|
| Reporting group title | RSV MAT Group - Mother |
| Reporting group description: | |
| Maternal participants received a single dose of the RSV MAT vaccine administered at Day 1 in this study. | |
| Reporting group title | Placebo Group - Mother |
| Reporting group description: | |
| Maternal participants received a single dose of placebo administered at Day 1 in this study. | |
| Reporting group title | RSV MAT Group - Infant |
| Reporting group description: | |
| This group consisted of infants born to mothers (from RSV MAT Group - Mother) who received a single dose of RSV MAT vaccine during pregnancy. | |
| Reporting group title | Placebo Group - Infant |
| Reporting group description: | |
| This group consisted of infants born to mothers (from Placebo Group - Mother) who received a single dose of placebo during pregnancy. | |

| Reporting group values | RSV MAT Group - Mother | Placebo Group - Mother | RSV MAT Group - Infant |
|----------------------------|------------------------|------------------------|------------------------|
| Number of subjects | 3557 | 1771 | 3494 |
| Age Categorical | | | |
| Units: Participants | | | |
| 0 to 1 years of age | 0 | 0 | 3494 |
| 18 to 34 years of age | 2866 | 1408 | 0 |
| 35 to 39 years of age | 581 | 300 | 0 |
| 40 to 49 years of age | 110 | 63 | 0 |
| Sex/Gender, Customized | | | |
| Units: Participants | | | |
| Female | 3557 | 1771 | 1739 |
| Male | 0 | 0 | 1753 |
| Other, Unspecified | 0 | 0 | 2 |
| Race/Ethnicity, Customized | | | |
| Units: Subjects | | | |
| ASIAN | 663 | 326 | 641 |
| BLACK OR AFRICAN AMERICAN | 517 | 251 | 463 |
| WHITE | 1669 | 838 | 1634 |
| OTHER, UNSPECIFIED | 685 | 345 | 730 |
| OTHER, DEIDENTIFIED | 23 | 11 | 26 |

| Reporting group values | Placebo Group - Infant | Total | |
|------------------------|------------------------|-------|--|
| Number of subjects | 1741 | 10563 | |
| Age Categorical | | | |
| Units: Participants | | | |
| 0 to 1 years of age | 1741 | 5235 | |
| 18 to 34 years of age | 0 | 4274 | |
| 35 to 39 years of age | 0 | 881 | |
| 40 to 49 years of age | 0 | 173 | |

| | | | |
|----------------------------|-----|------|--|
| Sex/Gender, Customized | | | |
| Units: Participants | | | |
| Female | 867 | 7934 | |
| Male | 873 | 2626 | |
| Other, Unspecified | 1 | 3 | |
| Race/Ethnicity, Customized | | | |
| Units: Subjects | | | |
| ASIAN | 321 | 1951 | |
| BLACK OR AFRICAN AMERICAN | 234 | 1465 | |
| WHITE | 816 | 4957 | |
| OTHER, UNSPECIFIED | 348 | 2108 | |
| OTHER, DEIDENTIFIED | 22 | 82 | |

End points

End points reporting groups

| | |
|---|------------------------|
| Reporting group title | RSV MAT Group - Mother |
| Reporting group description: Maternal participants received a single dose of the RSV MAT vaccine administered at Day 1 in this study. | |
| Reporting group title | Placebo Group - Mother |
| Reporting group description: Maternal participants received a single dose of placebo administered at Day 1 in this study. | |
| Reporting group title | RSV MAT Group - Infant |
| Reporting group description: This group consisted of infants born to mothers (from RSV MAT Group - Mother) who received a single dose of RSV MAT vaccine during pregnancy. | |
| Reporting group title | Placebo Group - Infant |
| Reporting group description: This group consisted of infants born to mothers (from Placebo Group - Mother) who received a single dose of placebo during pregnancy. | |
| Subject analysis set title | RSV MAT Group |
| Subject analysis set type | Per protocol |
| Subject analysis set description: This group consisted of pairs of maternal participants from RSV MAT Group - Mother and infant participants from RSV MAT Group - Infant. | |
| Subject analysis set title | Placebo Group |
| Subject analysis set type | Per protocol |
| Subject analysis set description: This group consisted of pairs of maternal participants from Placebo Group - Mother and infant participants from Placebo Group - Infant. | |

Primary: Number of infant participants with at least one serious adverse event (SAE) from birth to Day 181 post-birth

| | |
|--|--|
| End point title | Number of infant participants with at least one serious adverse event (SAE) from birth to Day 181 post-birth ^{[1][2]} |
| End point description: An SAE is defined as any untoward medical occurrence that resulted in death, was life-threatening, required hospitalization or prolongation of existing hospitalization, resulted in disability/incapacity, was a congenital anomaly/birth defect or resulted in other situations that were considered serious per medical or scientific judgment. At least one SAE = occurrence of at least one SAE regardless of intensity grade or relation to vaccination. The analysis was performed on the Exposed Set for infants, which included the infants live-born to exposed maternal participants, whose parents/legally acceptable representative(s) (LARs) completed the informed consent process and signed the informed consent form. | |
| End point type | Primary |
| End point timeframe: From birth to Day 181 post-birth | |

Notes:

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

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

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

Justification: This endpoint is only reporting values for the infant participants.

| End point values | RSV MAT Group - Infant | Placebo Group - Infant | | |
|-----------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3494 | 1741 | | |
| Units: Participants | 640 | 323 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of infant participants with medically assessed, RSV-associated lower respiratory tract illnesses (LRTIs) of any severity and RSV-associated severe LRTIs from birth to Day 181 post-birth

| | |
|-----------------|--|
| End point title | Number of infant participants with medically assessed, RSV-associated lower respiratory tract illnesses (LRTIs) of any severity and RSV-associated severe LRTIs from birth to Day 181 post-birth ^{[3][4]} |
|-----------------|--|

End point description:

An RSV-associated LRTI of any severity was characterized by a history of cough OR difficulty in breathing, AND a blood oxygen saturation by pulse oximetry (SpO2) lower than (<) 95%, OR respiratory rate increase AND a confirmed RSV infection. An RSV-associated severe LRTI met the case definition of RSV-LRTI AND was additionally characterized by an SpO2 <93%, OR lower chest wall in-drawing, OR inability to feed, OR failure to respond/unconscious. Medically assessed = the infant was evaluated by a healthcare professional for the LRTI.

The analysis was performed on the Modified Full Analysis - Efficacy set for infants, which included all infant participants in the Exposed set who were born after at least 4 weeks of their maternal participants vaccination.

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

End point timeframe:

From birth to Day 181 post-birth

Notes:

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

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

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

Justification: This endpoint is only reporting values for the infant participants.

| End point values | RSV MAT Group - Infant | Placebo Group - Infant | | |
|--------------------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3426 | 1711 | | |
| Units: Participants | | | | |
| RSV-associated LRTIs of any severity | 16 | 24 | | |
| RSV-associated severe LRTIs | 8 | 14 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of infant participants with at least one adverse event (AE) leading

to study withdrawal from birth to Day 181 post-birth

| | |
|-----------------|---|
| End point title | Number of infant participants with at least one adverse event (AE) leading to study withdrawal from birth to Day 181 post-birth ^{[5][6]} |
|-----------------|---|

End point description:

A participant was considered a 'withdrawal' from the study when no study procedure has occurred, no follow-up has been performed and no further information has been collected for this participant from the date of withdrawal/last contact. Participants who were withdrawn from the study because of AEs were clearly distinguished from participants who were withdrawn for other reasons. Investigators followed participants who were withdrawn from the study as a result of an AE until the event was resolved. At least one AE leading to study withdrawal = occurrence of at least one AE leading to study withdrawal regardless of intensity grade or relation to vaccination.

The analysis was performed on the Exposed Set for infants, which included the infants live-born to exposed maternal participants, whose parents/legally acceptable representative(s) (LARs) completed the informed consent process and signed the informed consent form.

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

End point timeframe:

From birth to Day 181 post-birth

Notes:

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

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

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

Justification: This endpoint is only reporting values for the infant participants.

| End point values | RSV MAT Group - Infant | Placebo Group - Infant | | |
|-----------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3494 | 1741 | | |
| Units: Participants | 19 | 4 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of infant participants with at least one medically attended AE (MAE) from birth to Day 181 post-birth

| | |
|-----------------|--|
| End point title | Number of infant participants with at least one medically attended AE (MAE) from birth to Day 181 post-birth ^{[7][8]} |
|-----------------|--|

End point description:

An MAE is defined as an unsolicited AE, such as a symptom or illness, which required hospitalization, or emergency room visit, or visit to/by a health care provider. At least one MAE = occurrence of at least one MAE regardless of intensity grade or relation to vaccination.

The analysis was performed on the Exposed Set for infants, which included the infants live-born to exposed maternal participants, whose parents/legally acceptable representative(s) (LARs) completed the informed consent process and signed the informed consent form.

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

End point timeframe:

From birth to Day 181 post-birth

Notes:

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

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the infant participants.

| End point values | RSV MAT Group - Infant | Placebo Group - Infant | | |
|-----------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3494 | 1741 | | |
| Units: Participants | 2321 | 1135 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of infant participants with at least one SAE from birth to Day 366 post-birth

| | |
|-----------------|---|
| End point title | Number of infant participants with at least one SAE from birth to Day 366 post-birth ^[9] ^[10] |
|-----------------|---|

End point description:

An SAE is defined as any untoward medical occurrence that resulted in death, was life-threatening, required hospitalization or prolongation of existing hospitalization, resulted in disability/incapacity, was a congenital anomaly/birth defect or resulted in other situations that were considered serious per medical or scientific judgment. At least one SAE = occurrence of at least one SAE regardless of intensity grade or relation to vaccination.

The analysis was performed on the Exposed Set for infants, which included the infants live-born to exposed maternal participants, whose parents/LARs completed the informed consent process and signed the informed consent form.

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

End point timeframe:

From birth to Day 366 post-birth

Notes:

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

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

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

Justification: This endpoint is only reporting values for the infant participants.

| End point values | RSV MAT Group - Infant | Placebo Group - Infant | | |
|-----------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3494 | 1741 | | |
| Units: Participants | 731 | 371 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of infant participants with at least one AE leading to study withdrawal from birth to Day 366 post-birth

| | |
|-----------------|---|
| End point title | Number of infant participants with at least one AE leading to study withdrawal from birth to Day 366 post-birth ^{[11][12]} |
|-----------------|---|

End point description:

A participant was considered a 'withdrawal' from the study when no study procedure has occurred, no follow-up has been performed and no further information has been collected for this participant from the date of withdrawal/last contact. Participants who were withdrawn from the study because of AEs were clearly distinguished from participants who were withdrawn for other reasons. Investigators followed participants who were withdrawn from the study as a result of an AE until the event was resolved. At least one AE leading to study withdrawal = occurrence of at least one AE leading to study withdrawal regardless of intensity grade or relation to vaccination.

The analysis was performed on the Exposed Set for infants, which included the infants live-born to exposed maternal participants, whose parents/LARs completed the informed consent process and signed the informed consent form.

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

End point timeframe:

From birth to Day 366 post-birth

Notes:

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

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

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

Justification: This endpoint is only reporting values for the infant participants.

| End point values | RSV MAT Group - Infant | Placebo Group - Infant | | |
|-----------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3494 | 1741 | | |
| Units: Participants | 21 | 4 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of infant participants with at least one MAE from birth to Day 366 post-birth

| | |
|-----------------|--|
| End point title | Number of infant participants with at least one MAE from birth to Day 366 post-birth ^{[13][14]} |
|-----------------|--|

End point description:

An MAE is defined as an unsolicited AE, such as a symptom or illness, which required hospitalization, or emergency room visit, or visit to/by a health care provider. At least one MAE = occurrence of at least one MAE regardless of intensity grade or relation to vaccination.

The analysis was performed on the Exposed Set for infants, which included the infants live-born to exposed maternal participants, whose parents/LARs completed the informed consent process and signed the informed consent form.

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

End point timeframe:

From birth to Day 366 post-birth

Notes:

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

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all

the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the infant participants.

| End point values | RSV MAT Group - Infant | Placebo Group - Infant | | |
|-----------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3494 | 1741 | | |
| Units: Participants | 2706 | 1330 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of infant participants with RSV-associated hospitalizations from birth to Day 181 post-birth

| | |
|-----------------|---|
| End point title | Number of infant participants with RSV-associated hospitalizations from birth to Day 181 post-birth ^[15] |
|-----------------|---|

End point description:

RSV-associated hospitalization is defined as a confirmed RSV infection and hospitalized for acute medical condition. Hospitalization is defined as admission for observation or treatment based on the judgment of a health care provider.

The analysis was performed on the Modified Full Analysis - Efficacy set for infants, which included all infant participants in the Exposed Set who were born after at least 4 weeks of their maternal participants vaccination.

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

End point timeframe:

From birth to Day 181 post-birth

Notes:

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

Justification: This endpoint is only reporting values for the infant participants.

| End point values | RSV MAT Group - Infant | Placebo Group - Infant | | |
|-----------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3426 | 1711 | | |
| Units: Participants | 14 | 14 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of infant participants with all-cause LRTIs from birth to Day 181 post-birth

| | |
|-----------------|---|
| End point title | Number of infant participants with all-cause LRTIs from birth to Day 181 post-birth ^[16] |
|-----------------|---|

End point description:

All-cause LRTI was characterized by history of cough OR difficulty in breathing, AND SpO₂ < 95%, OR respiratory rate increase.

The analysis was performed on the Modified Full Analysis - Efficacy set for infants, which included all the infant participants in the Exposed Set who were born after at least 4 weeks of their maternal participants vaccination.

| | |
|----------------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| From birth to Day 181 post-birth | |

Notes:

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

Justification: This endpoint is only reporting values for the infant participants.

| End point values | RSV MAT Group - Infant | Placebo Group - Infant | | |
|-----------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3426 | 1711 | | |
| Units: Participants | 162 | 103 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of infant participants with all-cause LRTIs with hospitalization from birth to Day 181 post-birth

| | |
|-----------------|--|
| End point title | Number of infant participants with all-cause LRTIs with hospitalization from birth to Day 181 post-birth ^[17] |
|-----------------|--|

End point description:

All-cause LRTI was characterized by history of cough OR difficulty in breathing, AND SpO2 < 95%, OR respiratory rate increase. Hospitalization is defined as admission for observation or treatment based on the judgment of a health care provider.

The analysis was performed on the Modified Full Analysis - Efficacy set for infants, which included all infant participants in the Exposed Set who were born after at least 4 weeks of their maternal participants vaccination.

| | |
|----------------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| From birth to Day 181 post-birth | |

Notes:

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

Justification: This endpoint is only reporting values for the infant participants.

| End point values | RSV MAT Group - Infant | Placebo Group - Infant | | |
|-----------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3426 | 1711 | | |
| Units: Participants | 30 | 22 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of infant participants with medically assessed, RSV-associated severe LRTIs from birth to Day 366 post-birth

| | |
|-----------------|---|
| End point title | Number of infant participants with medically assessed, RSV-associated severe LRTIs from birth to Day 366 post-birth ^[18] |
|-----------------|---|

End point description:

An RSV-associated LRTI of any severity was characterized by a history of cough OR difficulty in breathing, AND a SpO₂<95%, OR respiratory rate increase AND a confirmed RSV infection. An RSV-associated severe LRTI met the case definition of RSV-LRTI AND was additionally characterized by a SpO₂ <93%, OR lower chest wall in-drawing, OR inability to feed, OR failure to respond/unconscious. Medically assessed = the infant was evaluated by a healthcare professional for the LRTI. The analysis was performed on the Modified Full Analysis - Efficacy set for infants, which included all infant participants in the Exposed Set who were born after at least 4 weeks of their maternal participants vaccination.

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

End point timeframe:

From birth to Day 366 post-birth

Notes:

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

Justification: This endpoint is only reporting values for the infant participants.

| End point values | RSV MAT Group - Infant | Placebo Group - Infant | | |
|-----------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3426 | 1711 | | |
| Units: Participants | 38 | 22 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of infant participants with medically assessed, RSV-associated LRTIs of any severity from birth to Day 366 post-birth

| | |
|-----------------|--|
| End point title | Number of infant participants with medically assessed, RSV-associated LRTIs of any severity from birth to Day 366 post-birth ^[19] |
|-----------------|--|

End point description:

An RSV-associated LRTI of any severity was characterized by a history of cough OR difficulty in breathing, AND an SpO₂< 95%, OR respiratory rate increase AND a confirmed RSV infection. Medically assessed = the infant was evaluated by a healthcare professional for the LRTI. The analysis was performed on the Modified Full Analysis - Efficacy set for infants, which included all infant participants in the Exposed Set who were born after at least 4 weeks of their maternal participants vaccination.

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

End point timeframe:

From birth to Day 366 post-birth

Notes:

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

Justification: This endpoint is only reporting values for the infant participants.

| End point values | RSV MAT Group - Infant | Placebo Group - Infant | | |
|-----------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3426 | 1711 | | |
| Units: Participants | 67 | 43 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of infant participants with medically assessed, RSV-associated severe LRTIs for RSV subtype A and RSV subtype B separately from birth to Day 181 post-birth

| | |
|-----------------|--|
| End point title | Number of infant participants with medically assessed, RSV-associated severe LRTIs for RSV subtype A and RSV subtype B separately from birth to Day 181 post-birth ^[20] |
|-----------------|--|

End point description:

An RSV-associated LRTI of any severity was characterized by a history of cough OR difficulty in breathing, AND SpO₂<95%, OR respiratory rate increase AND a confirmed RSV infection. An RSV-associated severe LRTI met the case definition of RSV-LRTI AND was additionally characterized by a SpO₂ <93%, OR lower chest wall in-drawing, OR inability to feed, OR failure to respond/unconscious. Medically assessed = the infant was evaluated by a healthcare professional for the LRTI. The RSV subtypes assessed for this analysis were RSV subtype A and RSV subtype B. The analysis was performed on the Modified Full Analysis - Efficacy set for infants which included all the infant participants in the Exposed Set who were born after at least 4 weeks of their maternal participants vaccination.

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

End point timeframe:

From birth to Day 181 post-birth

Notes:

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

Justification: This endpoint is only reporting values for the infant participants.

| End point values | RSV MAT Group - Infant | Placebo Group - Infant | | |
|-----------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3426 | 1711 | | |
| Units: Participants | | | | |
| RSV A | 2 | 3 | | |
| RSV B | 6 | 11 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of infant participants with medically assessed, RSV-associated LRTIs of any severity for RSV subtype A and RSV subtype B separately from birth to Day 181 post-birth

| | |
|-----------------|---|
| End point title | Number of infant participants with medically assessed, RSV-associated LRTIs of any severity for RSV subtype A and RSV |
|-----------------|---|

End point description:

An RSV-associated LRTI of any severity was characterized by a history of cough OR difficulty in breathing, AND an SpO₂<95%, OR respiratory rate increase AND a confirmed RSV infection. Medically assessed = the infant was evaluated by a healthcare professional for the LRTI. The RSV subtypes assessed for this analysis were RSV subtype A and RSV subtype B.

The analysis was performed on the Modified Full Analysis - Efficacy set for infants, which included all infant participants in the Exposed Set who were born after at least 4 weeks of their maternal participants vaccination.

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

End point timeframe:

From birth to Day 181 post-birth

Notes:

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

Justification: This endpoint is only reporting values for the infant participants.

| End point values | RSV MAT Group - Infant | Placebo Group - Infant | | |
|-----------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3426 | 1711 | | |
| Units: Participants | | | | |
| RSV A | 6 | 8 | | |
| RSV B | 10 | 16 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of infant participants with medically assessed, RSV-associated severe LRTIs from birth to Day 121 post-birth

| | |
|-----------------|---|
| End point title | Number of infant participants with medically assessed, RSV-associated severe LRTIs from birth to Day 121 post-birth ^[22] |
|-----------------|---|

End point description:

An RSV-associated LRTI of any severity was characterized by a history of cough OR difficulty in breathing, AND an SpO₂<95%, OR respiratory rate increase AND a confirmed RSV infection. An RSV-associated severe LRTI met the case definition of RSV-LRTI AND was additionally characterized by an SpO₂<93%, OR lower chest wall in-drawing, OR inability to feed, OR failure to respond/unconscious. Medically assessed = the infant was evaluated by a healthcare professional for the LRTI.

The analysis was performed on the Modified Full Analysis - Efficacy set for infants, which included all infant participants in the Exposed Set who were born after at least 4 weeks of their maternal participants vaccination.

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

End point timeframe:

From birth to Day 121 post-birth

Notes:

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

Justification: This endpoint is only reporting values for the infant participants.

| End point values | RSV MAT Group - Infant | Placebo Group - Infant | | |
|-----------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3426 | 1711 | | |
| Units: Participants | 6 | 9 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of infant participants with medically assessed, RSV-associated LRTIs of any severity from birth to Day 121 post-birth

| | |
|-----------------|--|
| End point title | Number of infant participants with medically assessed, RSV-associated LRTIs of any severity from birth to Day 121 post-birth ^[23] |
|-----------------|--|

End point description:

An RSV-associated LRTI of any severity was characterized by a history of cough OR difficulty in breathing, AND a SpO₂<95%, OR respiratory rate increase AND a confirmed RSV infection. Medically assessed = the infant was evaluated by a healthcare professional for the LRTI.

The analysis was performed on the Modified Full Analysis - Efficacy set for infants, which included all infant participants in the Exposed Set who were born after at least 4 weeks of their maternal participants vaccination.

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

End point timeframe:

From birth to Day 121 post-birth

Notes:

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

Justification: This endpoint is only reporting values for the infant participants.

| End point values | RSV MAT Group - Infant | Placebo Group - Infant | | |
|-----------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3426 | 1711 | | |
| Units: Participants | 9 | 15 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of infant participants with all-cause pneumonia from birth to Day 181 post-birth

| | |
|-----------------|---|
| End point title | Number of infant participants with all-cause pneumonia from birth to Day 181 post-birth ^[24] |
|-----------------|---|

End point description:

The number of infant participants with all-cause pneumonia is presented in this endpoint.

The analysis was performed on the Modified Full Analysis - Efficacy set for infants, which included all infant participants in the Exposed Set who were born after at least 4 weeks of their maternal participants vaccination.

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

End point timeframe:

From birth to Day 181 post-birth

Notes:

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

Justification: This endpoint is only reporting values for the infant participants.

| End point values | RSV MAT Group - Infant | Placebo Group - Infant | | |
|-----------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3426 | 1711 | | |
| Units: Participants | 36 | 17 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of infant participants with RSV-associated hospitalizations from birth to Day 366 post-birth

| | |
|-----------------|---|
| End point title | Number of infant participants with RSV-associated hospitalizations from birth to Day 366 post-birth ^[25] |
|-----------------|---|

End point description:

RSV-associated hospitalization is defined as a confirmed RSV infection and hospitalized for acute medical condition. Hospitalization is defined as admission for observation or treatment based on the judgment of a health care provider.

The analysis was performed on the Modified Full Analysis - Efficacy set for infants, which included all infant participants in the Exposed Set who were born after at least 4 weeks of their maternal participants vaccination.

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

End point timeframe:

From birth to Day 366 post-birth

Notes:

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

Justification: This endpoint is only reporting values for the infant participants.

| End point values | RSV MAT Group - Infant | Placebo Group - Infant | | |
|-----------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3426 | 1711 | | |
| Units: Participants | 41 | 26 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-A neutralizing antibody titers for maternal participants at Day 1, Day 31 and at delivery

| | |
|-----------------|---|
| End point title | RSV-A neutralizing antibody titers for maternal participants at |
|-----------------|---|

End point description:

RSV-A neutralizing titers were determined by neutralization assay and expressed as geometric mean titers (GMTs).

The analysis was performed on the Per Protocol - Immunogenicity set for maternal participants, which included all maternal participants who received the study intervention to which they were randomized and had post-vaccination immunogenicity data available for the specified analysis at each of the specified time points (i.e. Day 1, Day 31, delivery) minus those participants with protocol deviations that led to exclusion.

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

End point timeframe:

At Day 1 (before study intervention administration), at Day 31 and at delivery

Notes:

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

Justification: This endpoint is only reporting values for the maternal participants.

| End point values | RSV MAT Group - Mother | Placebo Group - Mother | | |
|--|----------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 404 | 196 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Day 1 (N=404;196) | 637.2 (589.4 to 688.8) | 594.9 (527.3 to 671.2) | | |
| Day 31 (N=317;148) | 9196.9 (8310.8 to 10177.6) | 673.5 (578.8 to 783.7) | | |
| Delivery (N=404;178) | 5703.1 (5196.3 to 6259.3) | 657.7 (575.4 to 751.8) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with RSV-associated medically attended RTIs (RSV-MA-RTIs) from study intervention administration (Day 1) to Day 181 post-delivery

| | |
|-----------------|---|
| End point title | Number of maternal participants with RSV-associated medically attended RTIs (RSV-MA-RTIs) from study intervention administration (Day 1) to Day 181 post-delivery ^[27] |
|-----------------|---|

End point description:

RSV-associated MA-RTI is defined as a medically attended visit for RTI symptoms and confirmed RSV infection.

The analysis was performed on the Exposed Set for maternal participants, which included all maternal participants who received the study intervention.

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

End point timeframe:

From study intervention administration (Day 1) to Day 181 post-delivery

Notes:

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

Justification: This endpoint is only reporting values for the maternal participants.

| End point values | RSV MAT Group - Mother | Placebo Group - Mother | | |
|-----------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3557 | 1771 | | |
| Units: Participants | 3 | 6 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-A neutralizing antibody titers for infant participants at delivery or within 72 hours after birth

| | |
|-----------------|---|
| End point title | RSV-A neutralizing antibody titers for infant participants at delivery or within 72 hours after birth ^[28] |
|-----------------|---|

End point description:

RSV-A neutralizing titers were determined by neutralization assay and expressed as GMTs. The titers were measured on the cord blood sample collected at delivery, or on a blood sample collected from the infant within 72 hours after birth (if no cord blood sample could be obtained).

The analysis was performed on the Per Protocol - Immunogenicity set for infants, which included all infant participants in the Exposed set who had post-delivery/birth immunogenicity data available for the specified analysis at the specified time points (i.e. at delivery or within 72 hours after birth), minus those who (a) were born less than 4 weeks post- maternal participant vaccination and/ or (b) had protocol deviations that led to exclusion.

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

End point timeframe:

At delivery or within 72 hours after birth

Notes:

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

Justification: This endpoint is only reporting values for the infant participants.

| End point values | RSV MAT Group - Infant | Placebo Group - Infant | | |
|--|----------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 197 | 82 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | 9466.2 (8398.6 to 10669.5) | 725.9 (593.1 to 888.5) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-A neutralizing antibody titers for infant participants at Day 43 post-birth

| | |
|---|---|
| End point title | RSV-A neutralizing antibody titers for infant participants at Day 43 post-birth ^[29] |
| End point description: RSV-A neutralizing titers were determined by neutralization assay and expressed as GMTs. The analysis was performed on a sub-cohort from the Per Protocol - Immunogenicity set for infants, which included the infant participants for whom blood samples were collected for the specified analysis at Day 43 post-birth. | |
| End point type | Secondary |
| End point timeframe: At Day 43 post-birth | |

Notes:

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

Justification: This endpoint is only reporting values for the infant participants.

| End point values | RSV MAT Group - Infant | Placebo Group - Infant | | |
|--|---------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 140 | 67 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | 4042.1 (3530.3 to 4628.2) | 311.3 (250.3 to 387.2) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-A neutralizing antibody titers for infant participants at Day 121 post-birth

| | |
|--|--|
| End point title | RSV-A neutralizing antibody titers for infant participants at Day 121 post-birth ^[30] |
| End point description: RSV-A neutralizing titers were determined by neutralization assay and expressed as GMTs. The analysis was performed on a sub-cohort from the Per Protocol - Immunogenicity set for infants, which included the infant participants for whom blood samples were collected for the specified analysis at Day 121 post-birth. | |
| End point type | Secondary |
| End point timeframe: At Day 121 post-birth | |

Notes:

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

Justification: This endpoint is only reporting values for the infant participants.

| End point values | RSV MAT Group - Infant | Placebo Group - Infant | | |
|--|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 50 | 23 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | 682.4 (520.2 to 895.3) | 74.8 (46.5 to 120.2) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-A neutralizing antibody titers for infant participants at Day 181 post-birth

| | |
|-----------------|--|
| End point title | RSV-A neutralizing antibody titers for infant participants at Day 181 post-birth ^[31] |
|-----------------|--|

End point description:

RSV-A neutralizing titers were determined by neutralization assay and expressed as GMTs. The analysis was performed on a sub-cohort from the Per Protocol - Immunogenicity set for infants, which included the infant participants for whom blood samples were collected for the specified analysis at Day 181 post-birth.

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

End point timeframe:

At Day 181 post-birth

Notes:

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

Justification: This endpoint is only reporting values for the infant participants.

| End point values | RSV MAT Group - Infant | Placebo Group - Infant | | |
|--|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 44 | 9 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | 506.0 (432.4 to 592.3) | 133.7 (52.4 to 341.2) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric mean ratio (GMR) between cord blood and maternal RSV MAT immunoglobulin G (IgG)-specific antibody concentrations

| | |
|-----------------|--|
| End point title | Geometric mean ratio (GMR) between cord blood and maternal RSV MAT immunoglobulin G (IgG)-specific antibody concentrations |
|-----------------|--|

End point description:

The placental transfer ratio of RSV-MAT IgG-specific antibody concentration was determined from cord blood over that of the blood sample from mother at delivery. If no cord blood could be obtained, an infant blood sample was collected 72 hours after birth.

The analysis was performed on all pairs of maternal participants (from Per Protocol - Immunogenicity set for maternal participants) and their infants (from Per Protocol - Immunogenicity set for infants) with available results for this outcome measure at the specified time points.

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

End point timeframe:

At delivery (for maternal participants) or within 72 hours after birth (for infant participants, only if no cord blood could be obtained)

| End point values | RSV MAT Group | Placebo Group | | |
|--|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 150 | 60 | | |
| Units: Ratio | | | | |
| geometric mean (confidence interval 95%) | 1.46 (1.35 to 1.58) | 1.39 (1.22 to 1.59) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with any solicited administration site events from Day 1 to Day 7 included

| | |
|-----------------|--|
| End point title | Number of maternal participants with any solicited administration site events from Day 1 to Day 7 included ^[32] |
|-----------------|--|

End point description:

Assessed solicited administration site events included erythema, pain and swelling at the injection site. Any pain = occurrence of the symptom regardless of intensity grade. Any erythema and swelling = symptom reported with a surface diameter greater than or equal to 20 millimeters. The analysis was performed on the Solicited Safety set for maternal participants, which included all maternal participants who received the study intervention and who had solicited safety data available during the specified period (i.e. from Day 1 to Day 7 included).

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

End point timeframe:

From Day 1 to Day 7 included

Notes:

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

Justification: This endpoint is only reporting values for the maternal participants.

| End point values | RSV MAT Group - Mother | Placebo Group - Mother | | |
|-----------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3090 | 1547 | | |
| Units: Participants | | | | |
| Any Erythema | 133 | 8 | | |
| Any Pain | 1294 | 230 | | |
| Any Swelling | 96 | 8 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with any solicited systemic events from Day 1 to Day 7 included

| | |
|-----------------|---|
| End point title | Number of maternal participants with any solicited systemic events from Day 1 to Day 7 included ^[33] |
|-----------------|---|

End point description:

Assessed solicited systemic events included abdominal pain, diarrhea, fatigue, headache, nausea, fever [temperature equal to or above (\geq) 38 degrees Celsius ($^{\circ}$ C)/100.4 degrees Fahrenheit ($^{\circ}$ F), regardless of the location of measurement] and vomiting. Any = occurrence of the adverse event regardless of intensity grade or relation to study vaccination.

The analysis was performed on the Solicited Safety set for maternal participants, which included all maternal participants who received the study intervention and who had solicited safety data available during the specified period (i.e. from Day 1 to Day 7 included).

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

End point timeframe:

From Day 1 to Day 7 included

Notes:

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

Justification: This endpoint is only reporting values for the maternal participants.

| End point values | RSV MAT Group - Mother | Placebo Group - Mother | | |
|-----------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3090 | 1547 | | |
| Units: Participants | | | | |
| Any Abdominal pain | 492 | 231 | | |
| Any Diarrhea | 351 | 180 | | |
| Any Fatigue | 1091 | 479 | | |
| Any Headache | 942 | 442 | | |
| Any Nausea | 599 | 306 | | |
| Any Fever | 26 | 7 | | |
| Any Vomiting | 276 | 149 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with any unsolicited AEs from Day 1 to Day 30 included

| | |
|-----------------|--|
| End point title | Number of maternal participants with any unsolicited AEs from Day 1 to Day 30 included ^[34] |
|-----------------|--|

End point description:

An unsolicited AE is defined as any AE reported in addition to those solicited during the clinical study. Also, any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms was reported as an unsolicited AE. Any = occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination.

The analysis was performed on the Exposed Set for maternal participants, which included all maternal participants who received the study intervention.

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

End point timeframe:

From Day 1 to Day 30 included

Notes:

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

Justification: This endpoint is only reporting values for the maternal participants.

| End point values | RSV MAT Group - Mother | Placebo Group - Mother | | |
|-----------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3557 | 1771 | | |
| Units: Participants | 629 | 297 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with at least one SAE from Day 1 to Day 181 post-delivery

| | |
|-----------------|---|
| End point title | Number of maternal participants with at least one SAE from Day 1 to Day 181 post-delivery ^[35] |
|-----------------|---|

End point description:

An SAE is defined as any untoward medical occurrence that resulted in death, was life-threatening, required hospitalization or prolongation of existing hospitalization, resulted in disability/incapacity, was a congenital anomaly/birth defect in the offspring of a study participant or resulted in abnormal pregnancy outcomes or in other situations that were considered serious per medical or scientific judgment. At least one SAE = occurrence of at least one SAE regardless of intensity grade or relation to vaccination. The analysis was performed on the Exposed Set for maternal participants, which included all maternal participants who received the study intervention.

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

End point timeframe:

From Day 1 to Day 181 post-delivery

Notes:

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

Justification: This endpoint is only reporting values for the maternal participants.

| End point values | RSV MAT Group - Mother | Placebo Group - Mother | | |
|-----------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3557 | 1771 | | |
| Units: Participants | 827 | 395 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with at least one AE leading to study withdrawal from Day 1 to Day 181 post-delivery

| | |
|-----------------|--|
| End point title | Number of maternal participants with at least one AE leading to study withdrawal from Day 1 to Day 181 post-delivery ^[36] |
|-----------------|--|

End point description:

A participant was considered a 'withdrawal' from the study when no study procedure has occurred, no follow-up has been performed and no further information has been collected for this participant from the date of withdrawal/last contact. Participants who were withdrawn from the study because of AEs were clearly distinguished from participants who were withdrawn for other reasons. Investigators followed participants who were withdrawn from the study as a result of an AE until the event was resolved. At least one AE leading to study withdrawal = occurrence of at least one AE leading to study withdrawal regardless of intensity grade or relation to vaccination.

The analysis was performed on the Exposed Set for maternal participants, which included all maternal participants who received the study intervention.

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

End point timeframe:

From Day 1 to Day 181 post-delivery

Notes:

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

Justification: This endpoint is only reporting values for the maternal participants.

| End point values | RSV MAT Group - Mother | Placebo Group - Mother | | |
|-----------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3557 | 1771 | | |
| Units: Participants | 6 | 3 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with at least one all-cause MA-RTI from Day 1 to Day 181 post-delivery

| | |
|-----------------|--|
| End point title | Number of maternal participants with at least one all-cause MA-RTI from Day 1 to Day 181 post-delivery ^[37] |
|-----------------|--|

End point description:

All-cause MA-RTI occurred when the maternal participant visited a healthcare professional (e.g., a General Practitioner) for any respiratory symptom, including (but not limited to) cough, sore throat, sputum production and difficulty breathing. At least one all-cause MA-RTI = occurrence of at least one all-cause MA-RTI regardless of intensity grade or relation to vaccination.

The analysis was performed on the Exposed Set for maternal participants, which included all maternal participants who received the study intervention.

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

End point timeframe:

From Day 1 to Day 181 post-delivery

Notes:

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

Justification: This endpoint is only reporting values for the maternal participants.

| End point values | RSV MAT Group - Mother | Placebo Group - Mother | | |
|-----------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3557 | 1771 | | |
| Units: Participants | 317 | 144 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with at least one MAE from Day 1 to Day 42 post-delivery

| | |
|-----------------|--|
| End point title | Number of maternal participants with at least one MAE from Day 1 to Day 42 post-delivery ^[38] |
|-----------------|--|

End point description:

An MAE is defined as an unsolicited AE, such as a symptom or illness, which required hospitalization, or emergency room visit, or visit to/by a health care provider. At least one MAE = occurrence of at least one MAE regardless of intensity grade or relation to vaccination.

The analysis was performed on the Exposed Set for maternal participants, which included all maternal participants who received the study intervention.

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

End point timeframe:

From Day 1 to Day 42 post-delivery, an average of 2 months

Notes:

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

Justification: This endpoint is only reporting values for the maternal participants.

| End point values | RSV MAT Group - Mother | Placebo Group - Mother | | |
|-----------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3557 | 1771 | | |
| Units: Participants | 1717 | 785 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with pregnancy outcomes from Day 1 to Day 42 post-delivery

| | |
|-----------------|--|
| End point title | Number of maternal participants with pregnancy outcomes from Day 1 to Day 42 post-delivery ^[39] |
|-----------------|--|

End point description:

Assessed pregnancy outcomes included live birth (LB) with no congenital anomalies, live birth (LB) with minor congenital anomaly(ies), live birth (LB) with at least 1 major congenital anomaly, fetal death (FD)/still birth (SB) with no congenital anomalies, fetal death (FD)/still birth (SB) with at least 1 major congenital anomaly and unknown outcome (includes participants withdrawn before/at delivery with no available data of pregnancy outcomes).

The analysis was performed on the Exposed Set for maternal participants, which included all maternal participants who received the study intervention.

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

End point timeframe:

From Day 1 to Day 42 post-delivery, an average of 2 months

Notes:

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

Justification: This endpoint is only reporting values for the maternal participants.

| End point values | RSV MAT Group - Mother | Placebo Group - Mother | | |
|--|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3557 | 1771 | | |
| Units: Participants | | | | |
| LB with no congenital anomalies | 3118 | 1555 | | |
| LB with only minor congenital anomaly(ies) | 317 | 143 | | |
| LB with at least 1 major congenital anomaly | 61 | 43 | | |
| FD/SB with no congenital anomalies | 9 | 6 | | |
| FD/SB with at least 1 major congenital anomaly | 2 | 0 | | |
| Unknown outcome | 50 | 24 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with pregnancy-related adverse events of special interest (AESIs) from Day 1 to Day 42 post-delivery

| | |
|-----------------|--|
| End point title | Number of maternal participants with pregnancy-related adverse events of special interest (AESIs) from Day 1 to Day 42 post-delivery ^[40] |
|-----------------|--|

End point description:

Pregnancy-related AESIs included chorioamnionitis, fetal growth restriction, gestational diabetes mellitus, gestational hypertension, pre-eclampsia, pre-eclampsia with severe features including eclampsia, maternal death, premature preterm rupture of membranes, preterm labor, provider-initiated preterm birth.

The analysis was performed on the Exposed Set for maternal participants, which included all maternal participants who received the study intervention.

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

End point timeframe:

From Day 1 to Day 42 post-delivery, an average of 2 months

Notes:

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

Justification: This endpoint is only reporting values for the maternal participants.

| End point values | RSV MAT Group - Mother | Placebo Group - Mother | | |
|--|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3557 | 1771 | | |
| Units: Participants | | | | |
| Chorioamnionitis | 30 | 14 | | |
| Fetal Growth Restriction | 30 | 26 | | |
| Gestational Diabetes Mellitus | 42 | 19 | | |
| Gestational Hypertension | 85 | 41 | | |
| Pre-Eclampsia | 74 | 36 | | |
| Pre-Eclampsia With Severe Features | 58 | 28 | | |
| Maternal Death | 2 | 1 | | |
| Premature Preterm Rupture Of Membranes | 53 | 20 | | |
| Preterm Labor | 141 | 57 | | |
| Provider-Initiated Preterm Birth | 54 | 16 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of infant participants with neonatal AESIs from birth to Day 42 post-birth

| | |
|-----------------|---|
| End point title | Number of infant participants with neonatal AESIs from birth to Day 42 post-birth ^[41] |
|-----------------|---|

End point description:

Neonatal/infant AESIs included congenital anomalies with functional defects, congenital anomalies with internal structural defects, congenital anomalies with major external structural defects, extremely low birth weight (<1000 grams), low birth weight (<2500 grams), very low birth weight (<1500 grams), neonatal death in a preterm live birth (gestational age ≥ 28 and <37 weeks), neonatal death in a term live birth (≥ 37 weeks of gestational age), neonatal death in an extremely pre-term birth (gestational age ≥ 22 and <28 Weeks), preterm birth (<37 weeks of gestational age), small for gestational age. The analysis was performed on the Exposed Set for infants, which included infants live-born to exposed maternal participants, whose parents/LARs completed the informed consent process and signed the informed consent form.

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

End point timeframe:

From birth to Day 42 post-birth, an average of 2 months

Notes:

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

Justification: This endpoint is only reporting values for the infant participants.

| End point values | RSV MAT Group - Infant | Placebo Group - Infant | | |
|--|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3494 | 1741 | | |
| Units: Participants | | | | |
| CAs With Functional Defects | 5 | 2 | | |
| CAs With Internal Structural Defects | 23 | 16 | | |
| CAs With Major External Structural Defects | 24 | 14 | | |

| | | | | |
|---|-----|-----|--|--|
| Extremely Low Birth Weight (<1000 grams) | 3 | 0 | | |
| Low Birth Weight (<2500 grams) | 196 | 102 | | |
| Very Low Birth Weight (<1500 grams) | 5 | 0 | | |
| Neonatal Death In A Preterm Live Birth | 5 | 0 | | |
| Neonatal Death In A Term Live Birth | 6 | 3 | | |
| Neonatal Death In An Extremely Pre-Term Birth | 2 | 0 | | |
| Preterm Birth | 237 | 86 | | |
| Small For Gestational Age | 253 | 161 | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Maternal groups: Solicited AEs - from Day 1 to Day 7 and Unsolicited AEs - from Day 1 to Day 30 after vaccination. Deaths and SAEs - from Day 1 to Day 181 post-delivery. Infant groups: Deaths, SAEs and non SAEs - from birth to Day 366 post-birth.

Adverse event reporting additional description:

All events presented in the SAEs & Non SAEs modules are reported for the Exposed set for maternal participants & Exposed set for infants during the specified timeframe.

The solicited events presented for the RSV MAT Group – Mother & Placebo Group – Mother in the End Points module are reported for the Solicited safety set for maternal participants.

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

Dictionary used

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

Reporting groups

| | |
|-----------------------|------------------------|
| Reporting group title | RSV MAT Group - Mother |
|-----------------------|------------------------|

Reporting group description:

Maternal participants received a single dose of the RSV MAT vaccine administered at Day 1 in this study.

| | |
|-----------------------|------------------------|
| Reporting group title | Placebo Group - Infant |
|-----------------------|------------------------|

Reporting group description:

This group consisted of infants born to mothers (from Placebo Group - Mother) who received a single dose of placebo during pregnancy.

| | |
|-----------------------|------------------------|
| Reporting group title | RSV MAT Group - Infant |
|-----------------------|------------------------|

Reporting group description:

This group consisted of infants born to mothers (from RSV MAT Group - Mother) who received a single dose of RSV MAT vaccine during pregnancy.

| | |
|-----------------------|------------------------|
| Reporting group title | Placebo Group - Mother |
|-----------------------|------------------------|

Reporting group description:

Maternal participants received a single dose of placebo administered at Day 1 in this study.

| Serious adverse events | RSV MAT Group - Mother | Placebo Group - Infant | RSV MAT Group - Infant |
|---|------------------------|------------------------|------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 827 / 3557 (23.25%) | 371 / 1741 (21.31%) | 731 / 3494 (20.92%) |
| number of deaths (all causes) | 2 | 4 | 20 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Anogenital warts | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Granulosa cell tumour of the testis | | | |

| | | | |
|--|------------------|------------------|------------------|
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infantile haemangioma | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lymphoproliferative disorder | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malignant peritoneal neoplasm | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ovarian epithelial cancer | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Retinoblastoma | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| Aortic stenosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|------------------|------------------|------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood pressure fluctuation alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Deep vein thrombosis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haemodynamic instability alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypertensive crisis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypertension alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 3557 (0.08%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypotension alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-------------------|------------------|------------------|
| Neonatal hypotension alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renovascular hypertension alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Shock alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Subgaleal haematoma alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Venous thrombosis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| Surgical and medical procedures Medically induced preterm birth alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 37 / 3557 (1.04%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 1 / 37 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions Abortion spontaneous | | | |

| | | | |
|--|-------------------|------------------|------------------|
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abnormal labour | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 3557 (0.08%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Amniorrhoea | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Arrested labour | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 21 / 3557 (0.59%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 21 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Breech presentation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 20 / 3557 (0.56%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 20 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Caput succedaneum | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cephalo-pelvic disproportion | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|-------------------|------------------|------------------|
| subjects affected / exposed | 23 / 3557 (0.65%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 23 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cephalhaematoma alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cervix dystocia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 7 / 3557 (0.20%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eclampsia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Failed trial of labour alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Face presentation alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 3557 (0.08%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Failed induction of labour alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 27 / 3557 (0.76%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 27 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|--------------------|------------------|------------------|
| False labour alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 3557 (0.08%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foetal damage alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 5 / 3557 (0.14%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foetal disorder alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foetal dystocia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foetal growth restriction alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 17 / 3557 (0.48%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 17 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foetal distress syndrome alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 125 / 3557 (3.51%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 125 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foetal hypokinesia alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|-------------------|------------------|------------------|
| subjects affected / exposed | 9 / 3557 (0.25%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 1 / 9 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foetal macrosomia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 9 / 3557 (0.25%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foetal malpresentation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foetal malposition | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gestational diabetes | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 10 / 3557 (0.28%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gestational hypertension | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 46 / 3557 (1.29%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 46 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HELLP syndrome | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |

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| Haemorrhage in pregnancy alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 6 / 3557 (0.17%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hydrops foetalis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| High risk infant alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| High foetal head alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 3557 (0.08%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoxic ischaemic encephalopathy neonatal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 3 / 3494 (0.09%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypothermia neonatal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Jaundice neonatal alternative dictionary used: v26.1 26.1 | | | |

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|---|-------------------|-------------------|-------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 51 / 1741 (2.93%) | 89 / 3494 (2.55%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 51 | 0 / 91 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Large for dates baby alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 3 / 1741 (0.17%) | 3 / 3494 (0.09%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Labour complication alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Low birth weight baby alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 21 / 1741 (1.21%) | 53 / 3494 (1.52%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 21 | 1 / 53 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 5 |
| Maternal death alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| Meconium in amniotic fluid alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 15 / 3557 (0.42%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 15 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Morning sickness alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Obstructed labour alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 9 / 3557 (0.25%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Oligohydramnios alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 19 / 3557 (0.53%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 1 / 19 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pelvic haematoma obstetric alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Peripartum cardiomyopathy alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Placental polyp alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Placental insufficiency alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Placenta praevia alternative dictionary used: v26.1 26.1 | | | |

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|---|-------------------|-------------------|-------------------|
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Polyhydramnios alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Premature rupture of membranes alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 11 / 3557 (0.31%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Premature labour alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 56 / 3557 (1.57%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 2 / 56 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Premature baby alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 30 / 1741 (1.72%) | 84 / 3494 (2.40%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 30 | 1 / 84 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 4 |
| Precipitate labour alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Postpartum haemorrhage alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 46 / 3557 (1.29%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 47 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Pre-eclampsia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 105 / 3557 (2.95%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 106 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| Premature separation of placenta alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 9 / 3557 (0.25%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Prolonged labour alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 66 / 3557 (1.86%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 66 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Preterm premature rupture of membranes alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 37 / 3557 (1.04%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 37 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Prolonged pregnancy alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 8 / 3557 (0.22%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Prolonged rupture of membranes alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 11 / 3557 (0.31%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Retained placenta or membranes alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 9 / 3557 (0.25%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Retained products of conception alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Shoulder dystocia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 3557 (0.08%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Small for dates baby alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 15 / 1741 (0.86%) | 21 / 3494 (0.60%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 15 | 0 / 21 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| Stillbirth alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 11 / 3557 (0.31%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Threatened labour alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 28 / 3557 (0.79%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 30 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transverse presentation alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Traumatic delivery alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Umbilical cord around neck alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Umbilical cord prolapse alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Umbilical cord compression alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 6 / 3557 (0.17%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Uterine atony alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Uterine contractions during pregnancy alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Uterine hypertonus alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Uterine hypotonus alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Weight decrease neonatal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions Chest pain alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Crying alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Developmental delay alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Death neonatal alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 3 / 1741 (0.17%) | 13 / 3494 (0.37%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | 0 / 13 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 3 | 0 / 13 |
| Dysplasia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fatigue alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Feeling jittery alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Generalised oedema alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperthermia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypothermia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 5 / 3494 (0.14%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 5 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Inflammation alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Macrosomia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Multiple organ dysfunction syndrome alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyrexia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 6 / 1741 (0.34%) | 10 / 3494 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 6 | 0 / 10 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sudden death alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| Sudden infant death syndrome alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Immune system disorders ABO incompatibility alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 7 / 3494 (0.20%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 7 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Anaphylactic reaction alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood type incompatibility alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 3 / 1741 (0.17%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Milk allergy alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rhesus incompatibility alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders Abnormal uterine bleeding alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cervical dysplasia alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enlarged clitoris alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Genital labial adhesions alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pelvic haematoma alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Shortened cervix alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vaginal haemorrhage alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vaginal discharge alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Respiratory, thoracic and mediastinal disorders | | | |
| Adenoidal hypertrophy | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute respiratory failure | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Apnoea | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 3 / 3494 (0.09%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Atelectasis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Asthmatic crisis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Asthma | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Aspiration | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|---|------------------|------------------|------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Asphyxia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Bronchial obstruction alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 3 / 3494 (0.09%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchial hyperreactivity alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Brief resolved unexplained event alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchopulmonary dysplasia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Choking alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Chronic respiratory disease alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cough alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cyanosis neonatal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dyspnoea alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Epistaxis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoxia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infantile apnoea alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 3 / 3494 (0.09%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Laryngeal stenosis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Meconium aspiration syndrome alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 8 / 1741 (0.46%) | 10 / 3494 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 8 | 0 / 10 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| Neonatal aspiration alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Neonatal dyspnoea alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neonatal asphyxia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 3 / 1741 (0.17%) | 4 / 3494 (0.11%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| Neonatal pneumothorax alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Neonatal hypoxia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 3 / 3494 (0.09%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neonatal tachypnoea alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 3 / 3494 (0.09%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neonatal respiratory depression alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neonatal respiratory distress alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 31 / 1741 (1.78%) | 66 / 3494 (1.89%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 31 | 2 / 66 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Neonatal respiratory distress syndrome alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 7 / 1741 (0.40%) | 23 / 3494 (0.66%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 7 | 0 / 23 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| Neonatal pulmonary hypertension alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural effusion alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumothorax alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 3 / 1741 (0.17%) | 4 / 3494 (0.11%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Pulmonary artery stenosis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary embolism alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary hypertension alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 3 / 1741 (0.17%) | 4 / 3494 (0.11%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| Pulmonary venous hypertension alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary vein stenosis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Respiratory arrest alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory disorder neonatal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory depth decreased alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory depression alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Stridor alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tachypnoea alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transient tachypnoea of the newborn alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 16 / 1741 (0.92%) | 37 / 3494 (1.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 16 | 0 / 37 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Wheezing alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders Confusional state alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders Biliary colic alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Biliary dilatation alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholestasis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholelithiasis alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 4 / 3557 (0.11%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholecystitis acute alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 4 / 3557 (0.11%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholecystitis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 3557 (0.08%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholestasis of pregnancy alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 4 / 3557 (0.11%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gallbladder disorder alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gallbladder rupture alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis neonatal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Hyperbilirubinaemia neonatal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 14 / 1741 (0.80%) | 26 / 3494 (0.74%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 14 | 0 / 26 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperbilirubinaemia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| Apgar score low alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood pressure increased alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| C-reactive protein increased alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foetal heart rate abnormal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 3557 (0.08%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foetal heart rate decreased alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|------------------|------------------|------------------|
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foetal monitoring abnormal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gynaecological examination abnormal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haemoglobin decreased alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis B surface antigen positive alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Male genital examination abnormal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Medical observation alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 1 / 3557 (0.03%) | 3 / 1741 (0.17%) | 6 / 3494 (0.17%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | 0 / 6 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Oxygen saturation decreased alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral test positive alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Weight decreased alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Abdominal injury alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ankle fracture alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bladder injury alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Brachial plexus injury alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 3 / 3494 (0.09%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Clavicle fracture alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Contusion alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Exposure to SARS-CoV-2 alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Extradural haematoma alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Failed forceps delivery alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Face injury alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fall alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foetal exposure during delivery alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fracture of clavicle due to birth trauma alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fractured skull depressed alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Head injury alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Humerus fracture alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Joint dislocation alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Multiple fractures alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Perineal injury alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 3557 (0.08%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Post lumbar puncture syndrome alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Procedural haemorrhage alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skull fracture alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 3 / 3494 (0.09%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Subdural haemorrhage alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thermal burn alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tongue injury alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Traumatic haemorrhage alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Uterine cervical laceration alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Uterine rupture alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vulvovaginal injury alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Wound dehiscence alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 3557 (0.08%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Wound haematoma alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital, familial and genetic disorders | | | |
| Adrenogenital syndrome alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Aplasia cutis congenita alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anomalous pulmonary venous connection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Ankyloglossia congenital alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 7 / 1741 (0.40%) | 9 / 3494 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 7 | 0 / 9 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Arteriovenous malformation alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Atrial septal defect alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 10 / 1741 (0.57%) | 22 / 3494 (0.63%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 11 | 0 / 22 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Atrioventricular septal defect alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Biotinidase deficiency alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Bicuspid aortic valve alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Brachycephaly alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Branchial cyst alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Buried penis syndrome alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cataract congenital alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Choanal atresia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Chordee alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cleft lip alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital cerebral cyst alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Coarctation of the aorta alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cleft lip and palate alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital choroid plexus cyst alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital cystic kidney disease alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital diaphragmatic hernia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital ectopic bladder alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Congenital laryngeal stridor alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital great vessel anomaly alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital hydronephrosis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 4 / 3494 (0.11%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital inguinal hernia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital knee dislocation alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital facial diplegia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital melanosis alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital musculoskeletal disorder of skull | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital myasthenic syndrome | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital nephrotic syndrome | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital toxoplasmosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital pyelocaliectasis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital skin dimples | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|---|------------------|------------------|-------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital syphilis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 3 / 3494 (0.09%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital torticollis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital pneumonia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 5 / 1741 (0.29%) | 4 / 3494 (0.11%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 5 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Cryptorchism alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 5 / 1741 (0.29%) | 16 / 3494 (0.46%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 5 | 0 / 16 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Craniosynostosis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cystic fibrosis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Cytogenetic abnormality alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Developmental hip dysplasia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 9 / 1741 (0.52%) | 12 / 3494 (0.34%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 10 | 0 / 12 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dextrocardia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Disseminated neonatal herpes simplex alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Dysmorphism alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ectopic kidney alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Epispadias alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Erythroblastosis foetalis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fibromatosis colli of infancy alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Genitalia external ambiguous alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Glucose-6-phosphate dehydrogenase deficiency alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haemangioma congenital alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Heart disease congenital alternative dictionary used: v26.1 26.1 | | | |

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|---|------------------|------------------|------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 5 / 3494 (0.14%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 5 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Heterotaxia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Hypertelorism | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypospadias | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 6 / 1741 (0.34%) | 9 / 3494 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 6 | 0 / 9 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal malrotation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Iris coloboma | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Kidney duplex | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Laryngomalacia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Macrocephaly alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Macrostomia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Micrognathia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Microcephaly alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Menkes' syndrome alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Microtia alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Micropenis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Multiple congenital abnormalities alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myotonic dystrophy alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Newborn persistent pulmonary hypertension alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Oesophageal atresia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Osteochondrodysplasia alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Osteogenesis imperfecta | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pectus excavatum | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 7 / 3494 (0.20%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 7 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Patent ductus arteriosus | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 8 / 1741 (0.46%) | 3 / 3494 (0.09%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 8 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Penoscrotal fusion | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Penile torsion | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Polydactyly | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 4 / 1741 (0.23%) | 5 / 3494 (0.14%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | 0 / 5 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Pulmonary artery stenosis congenital alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 4 / 3494 (0.11%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyloric stenosis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal hypoplasia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Scaphocephaly alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Shone complex alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin hypoplasia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syndactyly alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syringomyelia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thalassaemia alpha alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Talipes alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 7 / 3494 (0.20%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 7 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Trisomy 21 alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Urachal abnormality alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular malformation alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Ventricular septal defect alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 5 / 1741 (0.29%) | 12 / 3494 (0.34%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | 0 / 12 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Cardiac disorders | | | |
| Acute left ventricular failure alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Arrhythmia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bradycardia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bradycardia foetal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 10 / 3557 (0.28%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bradycardia neonatal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Cardiac failure alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Cardiac arrest alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| Cardio-respiratory arrest alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Cardiogenic shock alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Foetal arrhythmia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foetal heart rate deceleration abnormality alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 11 / 3557 (0.31%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Left ventricular failure alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Left ventricular hypertrophy alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nonreassuring foetal heart rate pattern alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 19 / 3557 (0.53%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 19 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary valve stenosis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Right ventricular hypertrophy alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Supraventricular tachycardia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Supravalvular aortic stenosis alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tachycardia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tachycardia foetal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 5 / 3557 (0.14%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ventricular dysfunction alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Wolff-Parkinson-White syndrome alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Brain hypoxia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Cerebral ventricle dilatation alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cerebral cyst alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Encephalopathy neonatal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Extrapyramidal disorder alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile convulsion alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 7 / 3494 (0.20%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 7 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fontanelle bulging alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Generalised tonic-clonic seizure alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Headache alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infantile spasms alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infant irritability alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoxic-ischaemic encephalopathy alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 3 / 1741 (0.17%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intracranial aneurysm alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intraventricular haemorrhage neonatal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 3 / 3494 (0.09%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lacunar stroke alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Kernicterus | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Migraine | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Monoplegia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myoclonus | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neonatal seizure | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Poor sucking reflex | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Seizure like phenomena alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seizure alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 3 / 1741 (0.17%) | 4 / 3494 (0.11%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Subarachnoid haemorrhage alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Subependymal cyst alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 4 / 3494 (0.11%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tethered cord syndrome alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Unresponsive to stimuli alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia neonatal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anaemia macrocytic | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anaemia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 11 / 3557 (0.31%) | 1 / 1741 (0.06%) | 6 / 3494 (0.17%) |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 1 | 0 / 6 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Blood loss anaemia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Coagulopathy | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Disseminated intravascular coagulation | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| Febrile neutropenia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foetal anaemia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haemorrhagic disorder alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypersplenism alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Iron deficiency anaemia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Leukocytosis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Lymphadenopathy alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Polycythaemia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombocytopenia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombocytopenia neonatal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ear and labyrinth disorders | | | |
| Deafness bilateral alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Deafness unilateral alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vertigo alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Retinopathy of prematurity alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Abdominal distension alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 3557 (0.08%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain upper alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain lower alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 5 / 3557 (0.14%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal fistula alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diarrhoea alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 5 / 1741 (0.29%) | 3 / 3494 (0.09%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dysphagia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Food poisoning alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastritis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal pain alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Gastrooesophageal reflux disease alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 3 / 3494 (0.09%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haematemesis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haematochezia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haemorrhoids alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infantile colic alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ileus alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Inguinal hernia alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal obstruction alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal pseudo-obstruction alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nausea alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Necrotising colitis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Necrotising enterocolitis neonatal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Oesophageal stenosis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Obstructive pancreatitis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis relapsing alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Peptic ulcer alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Volvulus alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 3 / 3494 (0.09%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders Ecchymosis alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Erythema multiforme alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Erythema toxicum neonatorum alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Henoch-Schonlein purpura alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Melanoderma alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Umbilical haemorrhage alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders Acute kidney injury alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 1 / 3557 (0.03%) | 1 / 1741 (0.06%) | 3 / 3494 (0.09%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| Bladder perforation alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hydronephrosis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nephrolithiasis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pelvi-ureteric obstruction alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyelocaliectasis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 4 / 3494 (0.11%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal cyst alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Renal disorder in pregnancy alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ureteric stenosis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary retention alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract obstruction alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocrine disorders | | | |
| Adrenal insufficiency alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Goitre alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Rheumatoid arthritis | | | |

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| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Retrognathia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Torticollis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Trigger finger | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Abscess | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acarodermatitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abscess neck | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Adenovirus infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Amoebic dysentery alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Amniotic cavity infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 12 / 3557 (0.34%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal abscess alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Appendicitis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 4 / 3557 (0.11%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bacteraemia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Bacterial infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 5 / 3494 (0.14%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 5 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchiolitis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 24 / 1741 (1.38%) | 56 / 3494 (1.60%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 25 | 0 / 61 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Breast abscess alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COVID-19 pneumonia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 4 / 3557 (0.11%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| COVID-19 alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 8 / 3557 (0.22%) | 10 / 1741 (0.57%) | 22 / 3494 (0.63%) |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 11 | 0 / 22 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis bacterial alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis orbital alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Conjunctivitis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 3 / 3494 (0.09%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Croup infectious alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dacryocystitis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dengue fever alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Device related infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dysentery alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocarditis bacterial alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endometritis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 5 / 3557 (0.14%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ear infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Escherichia bacteraemia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Escherichia pyelonephritis alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Escherichia urinary tract infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Exanthema subitum alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis bacterial alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 3557 (0.08%) | 7 / 1741 (0.40%) | 9 / 3494 (0.26%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 7 | 0 / 9 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis adenovirus alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Genital herpes alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis norovirus alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis salmonella alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis viral alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Groin abscess alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Herpes simplex alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Impetigo alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Influenza alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal sepsis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Laryngitis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 5 / 3494 (0.14%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 5 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Leishmaniasis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection viral alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mastitis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 6 / 3557 (0.17%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mastoiditis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mastitis bacterial alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Measles alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Meningitis aseptic alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Meningitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Meningitis neonatal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Meningitis viral | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metapneumovirus bronchiolitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metapneumovirus infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myiasis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Nasopharyngitis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 4 / 3494 (0.11%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neonatal pneumonia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 3 / 1741 (0.17%) | 5 / 3494 (0.14%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | 0 / 5 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Neonatal infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 3 / 1741 (0.17%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Norovirus infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Omphalitis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ophthalmia neonatorum alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Oral candidiasis alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Oral herpes alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis externa alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Osteomyelitis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media acute alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Papilloma viral infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Parainfluenzae virus infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pharyngitis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pertussis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Periorbital cellulitis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pharyngotonsillitis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia adenoviral alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia alternative dictionary used: v26.1 26.1 | | | |

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|---|------------------|-------------------|-------------------|
| subjects affected / exposed | 4 / 3557 (0.11%) | 21 / 1741 (1.21%) | 46 / 3494 (1.32%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 22 | 0 / 53 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 2 |
| Pilonidal disease | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia aspiration | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia influenzal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia bacterial | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia parainfluenzae viral | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia pneumococcal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Pneumonia respiratory syncytial viral alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 9 / 3494 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 9 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia viral alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Post procedural pneumonia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Postoperative wound infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 7 / 3557 (0.20%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Postpartum sepsis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Puerperal infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Puerperal pyrexia alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 3 / 3557 (0.08%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyelonephritis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 4 / 3557 (0.11%) | 3 / 1741 (0.17%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyelonephritis acute alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rash pustular alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory tract infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 3 / 1741 (0.17%) | 3 / 3494 (0.09%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus bronchitis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Respiratory syncytial virus bronchiolitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 15 / 1741 (0.86%) | 19 / 3494 (0.54%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 15 | 0 / 19 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Salmonella bacteraemia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rhinovirus infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 3 / 3494 (0.09%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rotavirus infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rhinitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sepsis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Sepsis neonatal | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|------------------|-------------------|-------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 18 / 1741 (1.03%) | 46 / 3494 (1.32%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 19 | 0 / 46 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 4 |
| Septic shock alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 1 / 1741 (0.06%) | 3 / 3494 (0.09%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 3 |
| Streptococcal sepsis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 4 / 3494 (0.11%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Staphylococcal sepsis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| Syphilis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suspected COVID-19 alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Systemic viral infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|------------------|------------------|------------------|
| Thyroglossal cyst infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tonsillitis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tracheobronchitis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Umbilical sepsis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urachal sinus infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper respiratory tract infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 4 / 1741 (0.23%) | 4 / 3494 (0.11%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urosepsis alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|--|-------------------|------------------|-------------------|
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract infection neonatal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 14 / 3557 (0.39%) | 5 / 1741 (0.29%) | 25 / 3494 (0.72%) |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 5 | 0 / 28 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Varicella alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral rash alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral upper respiratory tract infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 4 / 3494 (0.11%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Wound infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Wound sepsis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Carnitine deficiency alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dehydration alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 8 / 1741 (0.46%) | 10 / 3494 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 8 | 0 / 10 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Failure to thrive alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 3 / 3494 (0.09%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Feeding disorder alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Food intolerance alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|------------------|------------------|-------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperglycaemia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia neonatal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 9 / 1741 (0.52%) | 27 / 3494 (0.77%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 9 | 0 / 27 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 5 / 1741 (0.29%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 5 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypervolaemia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypokalaemia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypomagnesaemia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| Hyponatraemia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malnutrition alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolic acidosis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neonatal hypocalcaemia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Underweight alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Weight gain poor alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---------------------------|--|--|
| Serious adverse events | Placebo Group - Mother | | |
| Total subjects affected by serious adverse events | | | |

| | | | |
|---|------------------------|--|--|
| subjects affected / exposed | 395 / 1771 (22.30%) | | |
| number of deaths (all causes) | 1 | | |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Anogenital warts | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Granulosa cell tumour of the testis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infantile haemangioma | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Lymphoproliferative disorder | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Malignant peritoneal neoplasm | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Ovarian epithelial cancer | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|------------------|--|--|
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Retinoblastoma | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vascular disorders | | | |
| Aortic stenosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood pressure fluctuation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Deep vein thrombosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Haemodynamic instability | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypertensive crisis | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|---|------------------|--|--|--|
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hypertension | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hypotension | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Neonatal hypotension | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Renovascular hypertension | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Shock | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Subgaleal haematoma | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

| | | | |
|--|---|--|--|
| <p>Venous thrombosis</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>0 / 1771 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p> | | |
| <p>Surgical and medical procedures</p> <p>Medically induced preterm birth</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>12 / 1771 (0.68%)</p> <p>0 / 12</p> <p>0 / 0</p> | | |
| <p>Pregnancy, puerperium and perinatal conditions</p> <p>Abortion spontaneous</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>0 / 1771 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p> | | |
| <p>Abnormal labour</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>0 / 1771 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p> | | |
| <p>Amniorrhoea</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>0 / 1771 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p> | | |
| <p>Arrested labour</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>9 / 1771 (0.51%)</p> <p>0 / 9</p> <p>0 / 0</p> | | |
| <p>Breech presentation</p> | | | |

| | | | | |
|--|-------------------|--|--|--|
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 5 / 1771 (0.28%) | | | |
| occurrences causally related to treatment / all | 0 / 5 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Caput succedaneum | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cephalo-pelvic disproportion | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 16 / 1771 (0.90%) | | | |
| occurrences causally related to treatment / all | 0 / 16 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cephalhaematoma | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cervix dystocia | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 4 / 1771 (0.23%) | | | |
| occurrences causally related to treatment / all | 0 / 4 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Eclampsia | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Failed trial of labour | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |

| | | | | |
|---|-------------------|--|--|--|
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Face presentation | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Failed induction of labour | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 12 / 1771 (0.68%) | | | |
| occurrences causally related to treatment / all | 0 / 12 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| False labour | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Foetal damage | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 5 / 1771 (0.28%) | | | |
| occurrences causally related to treatment / all | 0 / 5 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Foetal disorder | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Foetal dystocia | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|---|--|--|--|
| <p>Foetal growth restriction</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>13 / 1771 (0.73%)</p> <p>1 / 13</p> <p>0 / 0</p> | | | |
| <p>Foetal distress syndrome</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>69 / 1771 (3.90%)</p> <p>0 / 69</p> <p>0 / 0</p> | | | |
| <p>Foetal hypokinesia</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>2 / 1771 (0.11%)</p> <p>0 / 2</p> <p>0 / 0</p> | | | |
| <p>Foetal macrosomia</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>3 / 1771 (0.17%)</p> <p>0 / 3</p> <p>0 / 0</p> | | | |
| <p>Foetal malpresentation</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>0 / 1771 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p> | | | |
| <p>Foetal malposition</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>1 / 1771 (0.06%)</p> <p>0 / 1</p> <p>0 / 0</p> | | | |
| <p>Gestational diabetes</p> <p>alternative dictionary used: v26.1 26.1</p> | | | | |

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|---|-------------------|--|--|--|
| subjects affected / exposed | 2 / 1771 (0.11%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gestational hypertension alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 22 / 1771 (1.24%) | | | |
| occurrences causally related to treatment / all | 0 / 22 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| HELLP syndrome alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Haemorrhage in pregnancy alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hydrops foetalis alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| High risk infant alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| High foetal head alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|------------------|--|--|--|
| Hypoxic ischaemic encephalopathy neonatal | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hypothermia neonatal | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Jaundice neonatal | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Large for dates baby | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Labour complication | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Low birth weight baby | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Maternal death | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |

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|---|-------------------|--|--|--|
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 1 | | | |
| Meconium in amniotic fluid alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 6 / 1771 (0.34%) | | | |
| occurrences causally related to treatment / all | 0 / 6 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Morning sickness alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Obstructed labour alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Oligohydramnios alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 14 / 1771 (0.79%) | | | |
| occurrences causally related to treatment / all | 0 / 14 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pelvic haematoma obstetric alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Peripartum cardiomyopathy alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|--|-------------------|--|--|--|
| Placental polyp alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Placental insufficiency alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Placenta praevia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 1 | | | |
| Polyhydramnios alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Premature rupture of membranes alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 5 / 1771 (0.28%) | | | |
| occurrences causally related to treatment / all | 0 / 5 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Premature labour alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 15 / 1771 (0.85%) | | | |
| occurrences causally related to treatment / all | 0 / 15 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Premature baby alternative dictionary used: v26.1 26.1 | | | | |

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|---|-------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Precipitate labour alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Postpartum haemorrhage alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 26 / 1771 (1.47%) | | | |
| occurrences causally related to treatment / all | 0 / 27 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pre-eclampsia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 51 / 1771 (2.88%) | | | |
| occurrences causally related to treatment / all | 0 / 52 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Premature separation of placenta alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 8 / 1771 (0.45%) | | | |
| occurrences causally related to treatment / all | 0 / 8 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Prolonged labour alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 43 / 1771 (2.43%) | | | |
| occurrences causally related to treatment / all | 0 / 43 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Preterm premature rupture of membranes alternative dictionary used: v26.1 26.1 | | | | |

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|--|-------------------|--|--|--|
| subjects affected / exposed | 14 / 1771 (0.79%) | | | |
| occurrences causally related to treatment / all | 0 / 14 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Prolonged pregnancy alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 7 / 1771 (0.40%) | | | |
| occurrences causally related to treatment / all | 0 / 7 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Prolonged rupture of membranes alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 3 / 1771 (0.17%) | | | |
| occurrences causally related to treatment / all | 0 / 3 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Retained placenta or membranes alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 3 / 1771 (0.17%) | | | |
| occurrences causally related to treatment / all | 0 / 3 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Retained products of conception alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Shoulder dystocia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Small for dates baby alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|--|-------------------|--|--|--|
| Stillbirth alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 6 / 1771 (0.34%) | | | |
| occurrences causally related to treatment / all | 0 / 6 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Threatened labour alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 15 / 1771 (0.85%) | | | |
| occurrences causally related to treatment / all | 0 / 15 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Transverse presentation alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Traumatic delivery alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Umbilical cord around neck alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Umbilical cord prolapse alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Umbilical cord compression alternative dictionary used: v26.1 26.1 | | | | |

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|--|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Uterine atony | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Uterine contractions during pregnancy | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Uterine hypertonus | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Uterine hypotonus | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Weight decrease neonatal | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| General disorders and administration site conditions | | | | |
| Chest pain | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |

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|---|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Crying | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Developmental delay | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Death neonatal | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Dysplasia | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Fatigue | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Feeling jittery | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|------------------|--|--|--|
| Generalised oedema alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hyperthermia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hypothermia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Inflammation alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Macrosomia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Multiple organ dysfunction syndrome alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 1 | | | |
| Pyrexia alternative dictionary used: v26.1 26.1 | | | | |

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|---|------------------|--|--|
| subjects affected / exposed | 3 / 1771 (0.17%) | | |
| occurrences causally related to treatment / all | 0 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Sudden death | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Sudden infant death syndrome | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Immune system disorders | | | |
| ABO incompatibility | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Anaphylactic reaction | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood type incompatibility | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Milk allergy | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Rhesus incompatibility | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Reproductive system and breast disorders | | | |
| Abnormal uterine bleeding | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cervical dysplasia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Enlarged clitoris | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Genital labial adhesions | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pelvic haematoma | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|--|------------------|--|--|
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Shortened cervix alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vaginal haemorrhage alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vaginal discharge alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Adenoidal hypertrophy alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Acute respiratory failure alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Apnoea alternative dictionary used: v26.1 26.1 | | | |

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|---|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Atelectasis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Asthmatic crisis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Asthma | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Aspiration | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Asphyxia | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bronchial obstruction | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|--|------------------|--|--|--|
| Bronchial hyperreactivity alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Brief resolved unexplained event alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bronchopulmonary dysplasia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Choking alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Chronic respiratory disease alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cough alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cyanosis neonatal alternative dictionary used: v26.1 26.1 | | | | |

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|---|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Dyspnoea | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Epistaxis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hypoxia | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Infantile apnoea | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Laryngeal stenosis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Meconium aspiration syndrome | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|------------------|--|--|--|
| Neonatal aspiration alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Neonatal dyspnoea alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Neonatal asphyxia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Neonatal pneumothorax alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Neonatal hypoxia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Neonatal tachypnoea alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Neonatal respiratory depression alternative dictionary used: v26.1 26.1 | | | | |

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|---|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Neonatal respiratory distress alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Neonatal respiratory distress syndrome alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Neonatal pulmonary hypertension alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pleural effusion alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumothorax alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pulmonary artery stenosis alternative dictionary used: v26.1 26.1 | | | | |

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|---|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pulmonary embolism | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pulmonary hypertension | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pulmonary venous hypertension | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pulmonary vein stenosis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Respiratory arrest | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Respiratory disorder neonatal | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|--|------------------|--|--|--|
| Respiratory depth decreased alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Respiratory depression alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Stridor alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Tachypnoea alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Transient tachypnoea of the newborn alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Wheezing alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Psychiatric disorders Confusional state alternative dictionary used: v26.1 26.1 | | | | |

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|---|------------------|--|--|
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hepatobiliary disorders | | | |
| Biliary colic | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Biliary dilatation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cholestasis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cholelithiasis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cholecystitis acute | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cholecystitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|---|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cholestasis of pregnancy alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 3 / 1771 (0.17%) | | | |
| occurrences causally related to treatment / all | 0 / 3 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gallbladder disorder alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gallbladder rupture alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hepatitis neonatal alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hyperbilirubinaemia neonatal alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hyperbilirubinaemia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|------------------|--|--|--|
| Investigations | | | | |
| Apgar score low | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Blood pressure increased | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| C-reactive protein increased | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Foetal heart rate abnormal | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Foetal heart rate decreased | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Foetal monitoring abnormal | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gynaecological examination abnormal | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |

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|---|------------------|--|--|--|
| subjects affected / exposed | 2 / 1771 (0.11%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Haemoglobin decreased alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hepatitis B surface antigen positive alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Male genital examination abnormal alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Medical observation alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Oxygen saturation decreased alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Viral test positive alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|------------------------------------|--|--|--|
| Weight decreased alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 1771 (0.00%) 0 / 0 0 / 0 | | | |
| Injury, poisoning and procedural complications Abdominal injury alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 1771 (0.00%) 0 / 0 0 / 0 | | | |
| Ankle fracture alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 1771 (0.00%) 0 / 0 0 / 0 | | | |
| Bladder injury alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 1771 (0.06%) 0 / 1 0 / 0 | | | |
| Brachial plexus injury alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 1771 (0.00%) 0 / 0 0 / 0 | | | |
| Clavicle fracture alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 1771 (0.00%) 0 / 0 0 / 0 | | | |
| Contusion alternative dictionary used: v26.1 26.1 | | | | |

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|--|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Exposure to SARS-CoV-2 alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Extradural haematoma alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Failed forceps delivery alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Face injury alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Fall alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Foetal exposure during delivery alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|------------------|--|--|--|
| Fracture of clavicle due to birth trauma | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Fractured skull depressed | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Head injury | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Humerus fracture | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Joint dislocation | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Multiple fractures | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Perineal injury | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |

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|--|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Post lumbar puncture syndrome alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Procedural haemorrhage alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Skull fracture alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Subdural haemorrhage alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Thermal burn alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Tongue injury alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|---|--|--|--|
| <p>Traumatic haemorrhage</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>1 / 1771 (0.06%)</p> <p>0 / 1</p> <p>0 / 0</p> | | | |
| <p>Uterine cervical laceration</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>0 / 1771 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p> | | | |
| <p>Uterine rupture</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>0 / 1771 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p> | | | |
| <p>Vulvovaginal injury</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>0 / 1771 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p> | | | |
| <p>Wound dehiscence</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>0 / 1771 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p> | | | |
| <p>Wound haematoma</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>1 / 1771 (0.06%)</p> <p>0 / 1</p> <p>0 / 0</p> | | | |
| <p>Congenital, familial and genetic disorders</p> <p>Adrenogenital syndrome</p> <p>alternative dictionary used: v26.1 26.1</p> | | | | |

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|--|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Aplasia cutis congenita alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Anomalous pulmonary venous connection alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Ankyloglossia congenital alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Arteriovenous malformation alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Atrial septal defect alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Atrioventricular septal defect alternative dictionary used: v26.1 26.1 | | | | |

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|---|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Biotinidase deficiency alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bicuspid aortic valve alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Brachycephaly alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Branchial cyst alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Buried penis syndrome alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cataract congenital alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|--|------------------|--|--|--|
| Choanal atresia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Chordee alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cleft lip alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Congenital cerebral cyst alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Coarctation of the aorta alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cleft lip and palate alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Congenital choroid plexus cyst alternative dictionary used: v26.1 26.1 | | | | |

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|---|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Congenital cystic kidney disease alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Congenital diaphragmatic hernia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Congenital ectopic bladder alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Congenital laryngeal stridor alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Congenital great vessel anomaly alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Congenital hydronephrosis alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|------------------|--|--|--|
| Congenital inguinal hernia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Congenital knee dislocation alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Congenital facial diplegia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Congenital melanosis alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Congenital musculoskeletal disorder of skull alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Congenital myasthenic syndrome alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Congenital nephrotic syndrome alternative dictionary used: v26.1 26.1 | | | | |

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|---|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Congenital toxoplasmosis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Congenital pyelocaliectasis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Congenital skin dimples | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Congenital syphilis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Congenital torticollis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Congenital pneumonia | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|------------------------------------|--|--|--|
| Cryptorchism alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 1771 (0.00%) 0 / 0 0 / 0 | | | |
| Craniosynostosis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 1771 (0.00%) 0 / 0 0 / 0 | | | |
| Cystic fibrosis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 1771 (0.00%) 0 / 0 0 / 0 | | | |
| Cytogenetic abnormality alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 1771 (0.00%) 0 / 0 0 / 0 | | | |
| Developmental hip dysplasia alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 1771 (0.00%) 0 / 0 0 / 0 | | | |
| Dextrocardia alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 1771 (0.00%) 0 / 0 0 / 0 | | | |
| Disseminated neonatal herpes simplex alternative dictionary used: v26.1 26.1 | | | | |

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|---|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Dysmorphism | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Ectopic kidney | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Epispadias | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Erythroblastosis foetalis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Fibromatosis colli of infancy | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Genitalia external ambiguous | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|------------------|--|--|--|
| Glucose-6-phosphate dehydrogenase deficiency | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Haemangioma congenital | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Heart disease congenital | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Heterotaxia | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hypertelorism | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hypospadias | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Intestinal malrotation | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |

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|---|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Iris coloboma | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Kidney duplex | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Laryngomalacia | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Macrocephaly | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Macrostomia | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Micrognathia | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|------------------------------------|--|--|--|
| Microcephaly alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 1771 (0.00%) 0 / 0 0 / 0 | | | |
| Menkes' syndrome alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 1771 (0.00%) 0 / 0 0 / 0 | | | |
| Microtia alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 1771 (0.00%) 0 / 0 0 / 0 | | | |
| Micropenis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 1771 (0.00%) 0 / 0 0 / 0 | | | |
| Multiple congenital abnormalities alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 1771 (0.00%) 0 / 0 0 / 0 | | | |
| Myotonic dystrophy alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 1771 (0.00%) 0 / 0 0 / 0 | | | |
| Newborn persistent pulmonary hypertension alternative dictionary used: v26.1 26.1 | | | | |

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|---|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Oesophageal atresia | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Osteochondrodysplasia | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Osteogenesis imperfecta | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pectus excavatum | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Patent ductus arteriosus | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Penoscrotal fusion | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|--|------------------|--|--|--|
| Penile torsion alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Polydactyly alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pulmonary artery stenosis congenital alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pyloric stenosis alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Renal hypoplasia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Scaphocephaly alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Shone complex alternative dictionary used: v26.1 26.1 | | | | |

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|---|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Skin hypoplasia | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Syndactyly | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Syringomyelia | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Thalassaemia alpha | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Talipes | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Trisomy 21 | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|--|------------------|--|--|--|
| Urachal abnormality alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Vascular malformation alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Ventricular septal defect alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cardiac disorders | | | | |
| Acute left ventricular failure alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Arrhythmia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bradycardia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bradycardia foetal alternative dictionary used: v26.1 26.1 | | | | |

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|--|------------------|--|--|--|
| subjects affected / exposed | 4 / 1771 (0.23%) | | | |
| occurrences causally related to treatment / all | 0 / 4 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bradycardia neonatal alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cardiac failure alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cardiac arrest alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cardio-respiratory arrest alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cardiogenic shock alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Foetal arrhythmia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|------------------|--|--|--|
| Foetal heart rate deceleration abnormality | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 5 / 1771 (0.28%) | | | |
| occurrences causally related to treatment / all | 0 / 5 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Left ventricular failure | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Left ventricular hypertrophy | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Nonreassuring foetal heart rate pattern | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 7 / 1771 (0.40%) | | | |
| occurrences causally related to treatment / all | 0 / 7 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pulmonary valve stenosis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Right ventricular hypertrophy | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Supraventricular tachycardia | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |

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|--|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Supravalvular aortic stenosis alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Tachycardia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Tachycardia foetal alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 3 / 1771 (0.17%) | | | |
| occurrences causally related to treatment / all | 0 / 3 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Ventricular dysfunction alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Wolff-Parkinson-White syndrome alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Nervous system disorders Brain hypoxia alternative dictionary used: v26.1 26.1 | | | | |

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|--|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cerebral ventricle dilatation alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cerebral cyst alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Encephalopathy neonatal alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Extrapyramidal disorder alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Febrile convulsion alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Fontanelle bulging alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|--|------------------|--|--|--|
| Generalised tonic-clonic seizure alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Headache alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Infantile spasms alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Infant irritability alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hypoxic-ischaemic encephalopathy alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Intracranial aneurysm alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Intraventricular haemorrhage neonatal alternative dictionary used: v26.1 26.1 | | | | |

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|---|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Lacunar stroke | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Kernicterus | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Migraine | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Monoplegia | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Myoclonus | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Neonatal seizure | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|--|------------------|--|--|--|
| Poor sucking reflex alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Seizure like phenomena alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Seizure alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Subarachnoid haemorrhage alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Subependymal cyst alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Syncope alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Tethered cord syndrome alternative dictionary used: v26.1 26.1 | | | | |

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|---|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Unresponsive to stimuli | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood and lymphatic system disorders | | | |
| Anaemia neonatal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Anaemia macrocytic | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Anaemia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 1771 (0.17%) | | |
| occurrences causally related to treatment / all | 0 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood loss anaemia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Coagulopathy | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|---|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Disseminated intravascular coagulation | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Febrile neutropenia | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Foetal anaemia | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Haemorrhagic disorder | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hypersplenism | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Iron deficiency anaemia | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |

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|---|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Leukocytosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Lymphadenopathy | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Polycythaemia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Thrombocytopenia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Thrombocytopenia neonatal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Ear and labyrinth disorders | | | |
| Deafness bilateral | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|---|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Deafness unilateral | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vertigo | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Eye disorders | | | |
| Retinopathy of prematurity | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal disorders | | | |
| Abdominal distension | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Abdominal pain | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Abdominal pain upper | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|---|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Abdominal pain lower alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 3 / 1771 (0.17%) | | | |
| occurrences causally related to treatment / all | 0 / 4 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Anal fistula alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Constipation alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Diarrhoea alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Dysphagia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Food poisoning alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|--|------------------|--|--|--|
| Gastritis alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastrointestinal pain alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastrooesophageal reflux disease alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Haematemesis alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Haematochezia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Haemorrhoids alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Infantile colic alternative dictionary used: v26.1 26.1 | | | | |

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|---|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Ileus | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Inguinal hernia | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Intestinal obstruction | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Intestinal pseudo-obstruction | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Nausea | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Necrotising colitis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|--|------------------|--|--|--|
| Necrotising enterocolitis neonatal alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Oesophageal stenosis alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Obstructive pancreatitis alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pancreatitis alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pancreatitis relapsing alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Peptic ulcer alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Volvulus alternative dictionary used: v26.1 26.1 | | | | |

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|---|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Vomiting | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Skin and subcutaneous tissue disorders | | | | |
| Ecchymosis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Erythema multiforme | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Erythema toxicum neonatorum | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Henoch-Schonlein purpura | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Melanoderma | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |

| | | | |
|---|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Umbilical haemorrhage | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Bladder perforation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hydronephrosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Nephrolithiasis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pelvi-ureteric obstruction | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | | |
|---|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pyelocaliectasis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Renal cyst | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Renal disorder in pregnancy | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Ureteric stenosis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Urinary retention | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Urinary tract obstruction | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|------------------|--|--|
| Endocrine disorders | | | |
| Adrenal insufficiency | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Goitre | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Rheumatoid arthritis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Retrognathia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Torticollis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Trigger finger | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |

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|---|-------------------|--|--|--|
| Abscess | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Acarodermatitis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Abscess neck | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Adenovirus infection | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Amoebic dysentery | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Amniotic cavity infection | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 11 / 1771 (0.62%) | | | |
| occurrences causally related to treatment / all | 0 / 11 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Anal abscess | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |

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|---|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Appendicitis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bacteraemia | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bacterial infection | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bronchitis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bronchiolitis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Breast abscess | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|--|------------------|--|--|--|
| COVID-19 pneumonia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| COVID-19 alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bronchitis bacterial alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cellulitis alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cellulitis orbital alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Conjunctivitis alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Croup infectious alternative dictionary used: v26.1 26.1 | | | | |

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|---|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Dacryocystitis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Dengue fever | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Device related infection | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Dysentery | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Endocarditis bacterial | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Endometritis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 3 / 1771 (0.17%) | | | |
| occurrences causally related to treatment / all | 0 / 3 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|---|--|--|--|
| <p>Ear infection</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>0 / 1771 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p> | | | |
| <p>Escherichia bacteraemia</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>0 / 1771 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p> | | | |
| <p>Escherichia pyelonephritis</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>0 / 1771 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p> | | | |
| <p>Escherichia urinary tract infection</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>1 / 1771 (0.06%)</p> <p>0 / 1</p> <p>0 / 0</p> | | | |
| <p>Exanthema subitum</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>0 / 1771 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p> | | | |
| <p>Eye infection</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>0 / 1771 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p> | | | |
| <p>Gastroenteritis bacterial</p> <p>alternative dictionary used: v26.1 26.1</p> | | | | |

| | | | | |
|---|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastroenteritis alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastroenteritis adenovirus alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Genital herpes alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastroenteritis norovirus alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastroenteritis salmonella alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastrointestinal infection alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|------------------|--|--|--|
| Gastroenteritis viral alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Groin abscess alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Herpes simplex alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Impetigo alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Infection alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Influenza alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Intestinal sepsis alternative dictionary used: v26.1 26.1 | | | | |

| | | | | |
|---|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Laryngitis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Lower respiratory tract infection | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Leishmaniasis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Lower respiratory tract infection viral | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Mastitis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Mastoiditis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|------------------|--|--|--|
| Mastitis bacterial alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Measles alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Meningitis aseptic alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Meningitis alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Meningitis neonatal alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Meningitis viral alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Metapneumovirus bronchiolitis alternative dictionary used: v26.1 26.1 | | | | |

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|--|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Metapneumovirus infection alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Myiasis alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Nasopharyngitis alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Neonatal pneumonia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Neonatal infection alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Norovirus infection alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|---|--|--|--|
| <p>Omphalitis</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>0 / 1771 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p> | | | |
| <p>Ophthalmia neonatorum</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>0 / 1771 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p> | | | |
| <p>Oral candidiasis</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>0 / 1771 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p> | | | |
| <p>Oral herpes</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>0 / 1771 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p> | | | |
| <p>Otitis media</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>0 / 1771 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p> | | | |
| <p>Otitis externa</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>0 / 1771 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p> | | | |
| <p>Osteomyelitis</p> <p>alternative dictionary used: v26.1 26.1</p> | | | | |

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|---|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Otitis media acute | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Papilloma viral infection | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Parainfluenzae virus infection | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pharyngitis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pertussis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Periorbital cellulitis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|--|------------------|--|--|--|
| Pharyngotonsillitis alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia adenoviral alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pilonidal disease alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia aspiration alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia influenzal alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia bacterial alternative dictionary used: v26.1 26.1 | | | | |

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|--|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia parainfluenzae viral alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia pneumococcal alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia respiratory syncytial viral alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia viral alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Post procedural pneumonia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Postoperative wound infection alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|------------------|--|--|--|
| Postpartum sepsis alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Puerperal infection alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Puerperal pyrexia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pyelonephritis alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pyelonephritis acute alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 3 / 1771 (0.17%) | | | |
| occurrences causally related to treatment / all | 0 / 3 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Rash pustular alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Respiratory tract infection alternative dictionary used: v26.1 26.1 | | | | |

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|--|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Respiratory syncytial virus infection alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Respiratory syncytial virus bronchitis alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Respiratory syncytial virus bronchiolitis alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Salmonella bacteraemia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Rhinovirus infection alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Rotavirus infection alternative dictionary used: v26.1 26.1 | | | | |

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|---|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Rhinitis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Sepsis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Sepsis neonatal | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Septic shock | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Streptococcal sepsis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Staphylococcal sepsis | | | | |
| alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|------------------|--|--|--|
| Syphilis alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Suspected COVID-19 alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Systemic viral infection alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Thyroglossal cyst infection alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Tonsillitis alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Tracheobronchitis alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Umbilical sepsis alternative dictionary used: v26.1 26.1 | | | | |

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|--|-------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Urachal sinus infection alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Upper respiratory tract infection alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Urosepsis alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Urinary tract infection neonatal alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Urinary tract infection alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 11 / 1771 (0.62%) | | | |
| occurrences causally related to treatment / all | 0 / 11 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Varicella alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|--|--|--|--|--|
| Viral rash alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 1771 (0.00%) 0 / 0 0 / 0 | | | |
| Viral upper respiratory tract infection alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 1771 (0.00%) 0 / 0 0 / 0 | | | |
| Viral infection alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 1771 (0.00%) 0 / 0 0 / 0 | | | |
| Wound infection alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 1771 (0.00%) 0 / 0 0 / 0 | | | |
| Wound sepsis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 1771 (0.06%) 0 / 1 0 / 0 | | | |
| Metabolism and nutrition disorders Carnitine deficiency alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 1771 (0.00%) 0 / 0 0 / 0 | | | |
| Dehydration alternative dictionary used: v26.1 26.1 | | | | |

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|---|------------------|--|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Failure to thrive alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Feeding disorder alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Food intolerance alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hyperglycaemia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hypoglycaemia neonatal alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hypoglycaemia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|--|------------------|--|--|--|
| Hypervolaemia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hypokalaemia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hypomagnesaemia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hyponatraemia alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Malnutrition alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Metabolic acidosis alternative dictionary used: v26.1 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Neonatal hypocalcaemia alternative dictionary used: v26.1 26.1 | | | | |

| | | | |
|---|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Underweight | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Weight gain poor | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| Non-serious adverse events | RSV MAT Group - Mother | Placebo Group - Infant | RSV MAT Group - Infant |
|---|-------------------------------|-------------------------------|-------------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 2262 / 3557 (63.59%) | 1389 / 1741 (79.78%) | 2802 / 3494 (80.19%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Acrochordon | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 3 / 3494 (0.09%) |
| occurrences (all) | 0 | 1 | 3 |
| Anogenital warts | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Haemangioma of skin | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 5 / 3494 (0.14%) |
| occurrences (all) | 0 | 0 | 5 |
| Haemangioma | | | |

| | | | |
|--|------------------|------------------|------------------|
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 4 / 1741 (0.23%) | 7 / 3494 (0.20%) |
| occurrences (all) | 0 | 4 | 7 |
| Infantile haemangioma | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 2 | 2 |
| Lipoma | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Melanocytic naevus | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 3 / 1741 (0.17%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 3 | 1 |
| Ocular neoplasm | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pyogenic granuloma | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Skin papilloma | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Ulcerated haemangioma | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Xanthogranuloma | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|------------------|------------------|------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vascular disorders | | | |
| Angiopathy | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cyanosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 3 / 3494 (0.09%) |
| occurrences (all) | 0 | 2 | 3 |
| Haematoma | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Hot flush | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Hypertension | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypotension | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Varicose vein | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 2 | 0 | 1 |
| Vasodilatation | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|--|-----------------------|-----------------------|-------------------------|
| subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 1 / 1741 (0.06%) 1 | 0 / 3494 (0.00%) 0 |
| Surgical and medical procedures Medically induced preterm birth alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 2 / 3557 (0.06%) 2 | 0 / 1741 (0.00%) 0 | 0 / 3494 (0.00%) 0 |
| Pregnancy, puerperium and perinatal conditions Birth trauma alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 1 / 3494 (0.03%) 1 |
| Breech presentation alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 3 / 3557 (0.08%) 3 | 0 / 1741 (0.00%) 0 | 0 / 3494 (0.00%) 0 |
| Caput succedaneum alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 4 / 1741 (0.23%) 4 | 10 / 3494 (0.29%) 10 |
| Cephalhaematoma alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 8 / 1741 (0.46%) 8 | 13 / 3494 (0.37%) 13 |
| Cephalo-pelvic disproportion alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 2 / 3557 (0.06%) 2 | 0 / 1741 (0.00%) 0 | 0 / 3494 (0.00%) 0 |
| Complication of delivery alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 1 / 3494 (0.03%) 1 |
| Complication of pregnancy alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|-------------------|------------------|------------------|
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| False labour | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Foetal acidosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Foetal distress syndrome | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Foetal growth restriction | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 4 / 3557 (0.11%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Foetal hypokinesia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 6 / 3557 (0.17%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 7 | 0 | 0 |
| Foetal macrosomia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Foetal malpresentation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gestational diabetes | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 23 / 3557 (0.65%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 23 | 0 | 0 |

| | | | |
|---|------------------|-------------------|--------------------|
| Gestational hypertension alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 5 / 3557 (0.14%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 5 | 0 | 0 |
| Haemorrhage in pregnancy alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypothermia neonatal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Jaundice neonatal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 95 / 1741 (5.46%) | 251 / 3494 (7.18%) |
| occurrences (all) | 0 | 95 | 252 |
| Large for dates baby alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 20 / 1741 (1.15%) | 27 / 3494 (0.77%) |
| occurrences (all) | 0 | 20 | 27 |
| Low birth weight baby alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 82 / 1741 (4.71%) | 151 / 3494 (4.32%) |
| occurrences (all) | 0 | 82 | 151 |
| Meconium stain alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 4 / 3494 (0.11%) |
| occurrences (all) | 0 | 1 | 4 |
| Maternal condition affecting foetus alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Meconium in amniotic fluid alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|------------------|------------------|------------------|
| subjects affected / exposed | 1 / 3557 (0.03%) | 1 / 1741 (0.06%) | 4 / 3494 (0.11%) |
| occurrences (all) | 1 | 1 | 4 |
| Morning sickness | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neonatal disorder | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Oligohydramnios | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Omphalorrhexis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Placenta praevia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Placental disorder | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Premature rupture of membranes | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Poor weight gain neonatal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 1 | 2 |

| | | | |
|---|-------------------|-------------------|--------------------|
| Postpartum haemorrhage alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pre-eclampsia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Premature baby alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 56 / 1741 (3.22%) | 153 / 3494 (4.38%) |
| occurrences (all) | 0 | 56 | 153 |
| Premature labour alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 18 / 3557 (0.51%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 18 | 0 | 0 |
| Polyhydramnios alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Prolonged labour alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Preterm premature rupture of membranes alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 6 / 3557 (0.17%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 6 | 0 | 0 |
| Retained placenta or membranes alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Shoulder dystocia alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|------------------|--------------------|--------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 5 / 3494 (0.14%) |
| occurrences (all) | 0 | 2 | 5 |
| Small for dates baby | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 147 / 1741 (8.44%) | 233 / 3494 (6.67%) |
| occurrences (all) | 0 | 147 | 233 |
| Threatened labour | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 3557 (0.08%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Umbilical cord around neck | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 4 / 3494 (0.11%) |
| occurrences (all) | 0 | 1 | 4 |
| Umbilical cord abnormality | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Umbilical granuloma | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 6 / 1741 (0.34%) | 12 / 3494 (0.34%) |
| occurrences (all) | 0 | 6 | 12 |
| Umbilical cord haemorrhage | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Uterine hypotonus | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Uterine irritability | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|--|---|---|---|
| <p>Uterine contractions during pregnancy</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>8 / 3557 (0.22%)</p> <p>8</p> | <p>0 / 1741 (0.00%)</p> <p>0</p> | <p>0 / 3494 (0.00%)</p> <p>0</p> |
| <p>Weight decrease neonatal</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 3557 (0.00%)</p> <p>0</p> | <p>2 / 1741 (0.11%)</p> <p>2</p> | <p>2 / 3494 (0.06%)</p> <p>2</p> |
| <p>General disorders and administration site conditions</p> <p>Administration site erythema</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Administration site pain</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>133 / 3557 (3.74%)</p> <p>133</p> <p>1294 / 3557 (36.38%)</p> <p>1294</p> | <p>0 / 1741 (0.00%)</p> <p>0</p> <p>0 / 1741 (0.00%)</p> <p>0</p> | <p>0 / 3494 (0.00%)</p> <p>0</p> <p>0 / 3494 (0.00%)</p> <p>0</p> |
| <p>Administration site swelling</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Adverse food reaction</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Asthenia</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Chills</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Crepitations</p> | <p>96 / 3557 (2.70%)</p> <p>96</p> <p>0 / 3557 (0.00%)</p> <p>0</p> <p>2 / 3557 (0.06%)</p> <p>2</p> <p>0 / 3557 (0.00%)</p> <p>0</p> | <p>0 / 1741 (0.00%)</p> <p>0</p> <p>0 / 1741 (0.00%)</p> <p>0</p> <p>0 / 1741 (0.00%)</p> <p>0</p> <p>2 / 1741 (0.11%)</p> <p>2</p> | <p>0 / 3494 (0.00%)</p> <p>0</p> <p>1 / 3494 (0.03%)</p> <p>1</p> <p>0 / 3494 (0.00%)</p> <p>0</p> <p>5 / 3494 (0.14%)</p> <p>5</p> |

| | | | |
|--|------------------|------------------|------------------|
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Crying | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 3 / 1741 (0.17%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 3 | 1 |
| Cyst | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Developmental delay | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 2 | 2 |
| Discomfort | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Feeling hot | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Feeling jittery | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Fever neonatal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Fatigue | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|-------------------------|------------------|------------------|
| subjects affected / exposed | 1093 / 3557 (30.73%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1093 | 0 | 0 |
| High-pitched crying alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypertrophy alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Hyperthermia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 4 / 3494 (0.11%) |
| occurrences (all) | 0 | 1 | 4 |
| Hypothermia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 2 |
| Illness alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Ill-defined disorder alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Injection site swelling alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 1 | 0 | 1 |
| Injection site pruritus alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|------------------|-------------------|-------------------|
| Injection site pain alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 4 / 3557 (0.11%) | 2 / 1741 (0.11%) | 3 / 3494 (0.09%) |
| occurrences (all) | 4 | 3 | 5 |
| Injection site oedema alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Injection site erythema alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 3557 (0.08%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 3 | 0 | 1 |
| Injection site bruising alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza like illness alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 12 / 1741 (0.69%) | 19 / 3494 (0.54%) |
| occurrences (all) | 1 | 27 | 44 |
| Irritability postvaccinal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 9 / 1741 (0.52%) | 9 / 3494 (0.26%) |
| occurrences (all) | 0 | 14 | 13 |
| Injury associated with device alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Macrosomia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 15 / 1741 (0.86%) | 17 / 3494 (0.49%) |
| occurrences (all) | 0 | 15 | 17 |
| Malaise alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|-------------------|-------------------|--------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Oedema | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Oedema peripheral | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Pain | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 1 | 0 | 1 |
| Peripheral swelling | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Puncture site pain | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pyrexia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 27 / 3557 (0.76%) | 81 / 1741 (4.65%) | 191 / 3494 (5.47%) |
| occurrences (all) | 27 | 98 | 219 |
| Swelling | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 4 / 1741 (0.23%) | 4 / 3494 (0.11%) |
| occurrences (all) | 0 | 4 | 4 |
| Swelling face | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |

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|--|-----------------------|-----------------------|-----------------------|
| Thirst alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 1 / 1741 (0.06%) 1 | 0 / 3494 (0.00%) 0 |
| Vaccination site induration alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 1 / 3494 (0.03%) 1 |
| Vaccination site pain alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 1 / 3557 (0.03%) 1 | 1 / 1741 (0.06%) 1 | 1 / 3494 (0.03%) 1 |
| Vessel puncture site bruise alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 1 / 3494 (0.03%) 1 |
| Vessel puncture site pain alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 1 / 3557 (0.03%) 1 | 0 / 1741 (0.00%) 0 | 0 / 3494 (0.00%) 0 |
| Immune system disorders ABO incompatibility alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 4 / 3494 (0.11%) 4 |
| Allergy to arthropod bite alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 1 / 1741 (0.06%) 1 | 0 / 3494 (0.00%) 0 |
| Allergy to arthropod sting alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 1 / 1741 (0.06%) 1 | 0 / 3494 (0.00%) 0 |
| Allergy to chemicals alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|------------------|------------------|-------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Allergy to vaccine | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Alloimmunisation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Atopy | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Drug hypersensitivity | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Food allergy | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 7 / 1741 (0.40%) | 16 / 3494 (0.46%) |
| occurrences (all) | 0 | 7 | 16 |
| Hypersensitivity | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 3 / 1741 (0.17%) | 7 / 3494 (0.20%) |
| occurrences (all) | 1 | 3 | 7 |
| Milk allergy | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 7 / 1741 (0.40%) | 18 / 3494 (0.52%) |
| occurrences (all) | 0 | 7 | 18 |
| Multiple allergies | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 1 | 2 |

| | | | |
|---|-----------------------|-----------------------|-----------------------|
| Nutritional supplement allergy alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) Rhesus incompatibility alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) Seasonal allergy alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| | 0 | 0 | 1 |
| | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| | 0 | 0 | 1 |
| | 1 / 3557 (0.03%) | 1 / 1741 (0.06%) | 5 / 3494 (0.14%) |
| | 1 | 1 | 5 |
| | | | |
| | | | |
| | | | |
| Reproductive system and breast disorders | | | |
| Acquired phimosis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 1 / 3494 (0.03%) 1 |
| Adnexa uteri cyst alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 0 / 3494 (0.00%) 0 |
| Balanoposthitis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 2 / 1741 (0.11%) 2 | 1 / 3494 (0.03%) 1 |
| Bilateral breast buds alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 2 / 1741 (0.11%) 2 | 1 / 3494 (0.03%) 1 |
| Coital bleeding alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 0 / 3494 (0.00%) 0 |
| Galactostasis alternative dictionary used: v26.1 | | | |

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| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Genital blister | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Genital discomfort | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Genital labial adhesions | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 3 / 1741 (0.17%) | 9 / 3494 (0.26%) |
| occurrences (all) | 0 | 3 | 9 |
| Genital macule | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Genital prolapse | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Genital ulceration | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gynaecomastia | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Ovarian cyst | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |

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|---|------------------|------------------|------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Penile adhesion | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Pelvic pain | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 3557 (0.08%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Pruritus genital | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Scrotal swelling | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Testicular retraction | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 2 | 1 |
| Vaginal discharge | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 8 / 3557 (0.22%) | 2 / 1741 (0.11%) | 1 / 3494 (0.03%) |
| occurrences (all) | 8 | 2 | 1 |
| Vaginal disorder | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 2 | 0 | 1 |
| Vaginal haemorrhage | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 6 / 3557 (0.17%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 6 | 0 | 1 |

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| Vulvovaginal erythema alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| | 0 | 0 | 1 |
| | | | |
| | | | |
| | | | |
| Vulval oedema alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| | 1 | 0 | 0 |
| | | | |
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| Vulvovaginal pain alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| | 1 | 0 | 0 |
| | | | |
| | | | |
| | | | |
| Vulvovaginal pruritus alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| | 1 | 0 | 0 |
| | | | |
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| | | | |
| Respiratory, thoracic and mediastinal disorders Adenoidal hypertrophy alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) Apnoea alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) Apnoeic attack alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) Asthma alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) Atelectasis alternative dictionary used: v26.1 | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| | 0 | 1 | 2 |
| | | | |
| | | | |
| | | | |
| | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| | 0 | 0 | 2 |
| | | | |
| | | | |
| | | | |
| | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| | 0 | 0 | 1 |
| | | | |
| | | | |
| | | | |
| | 1 / 3557 (0.03%) | 6 / 1741 (0.34%) | 8 / 3494 (0.23%) |
| | 1 | 6 | 8 |
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| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Asthmatic crisis | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Brief resolved unexplained event | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Bronchial hyperreactivity | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 4 / 1741 (0.23%) | 8 / 3494 (0.23%) |
| occurrences (all) | 0 | 4 | 9 |
| Bronchial obstruction | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 5 / 1741 (0.29%) | 20 / 3494 (0.57%) |
| occurrences (all) | 0 | 6 | 31 |
| Bronchiolitis obliterans syndrome | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Bronchitis chronic | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Bronchospasm | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 10 / 1741 (0.57%) | 13 / 3494 (0.37%) |
| occurrences (all) | 0 | 12 | 15 |
| Catarrh | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |

| | | | |
|---|------------------|--------------------|--------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 6 / 1741 (0.34%) | 8 / 3494 (0.23%) |
| occurrences (all) | 0 | 9 | 12 |
| Choking | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 2 | 2 |
| Childhood asthma | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Cough | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 4 / 3557 (0.11%) | 124 / 1741 (7.12%) | 243 / 3494 (6.95%) |
| occurrences (all) | 4 | 167 | 356 |
| Dyspnoea | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 3557 (0.08%) | 19 / 1741 (1.09%) | 20 / 3494 (0.57%) |
| occurrences (all) | 4 | 21 | 25 |
| Dysphonia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 1 | 2 |
| Epistaxis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Hyperventilation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypoxia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|--|-----------------------|--------------------------|---------------------------|
| Infantile apnoea alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 1 / 1741 (0.06%) 1 | 1 / 3494 (0.03%) 1 |
| Increased bronchial secretion alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 1 / 1741 (0.06%) 1 | 0 / 3494 (0.00%) 0 |
| Lower respiratory tract congestion alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 1 / 1741 (0.06%) 1 | 0 / 3494 (0.00%) 0 |
| Meconium aspiration syndrome alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 2 / 1741 (0.11%) 2 | 1 / 3494 (0.03%) 1 |
| Nasal congestion alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 4 / 3557 (0.11%) 4 | 93 / 1741 (5.34%) 112 | 223 / 3494 (6.38%) 269 |
| Nasal discomfort alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 1 / 3494 (0.03%) 1 |
| Nasal disorder alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 6 / 1741 (0.34%) 6 | 7 / 3494 (0.20%) 9 |
| Nasal dryness alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 1 / 3494 (0.03%) 1 |
| Nasal obstruction alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|------------------|------------------|-------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 4 / 1741 (0.23%) | 8 / 3494 (0.23%) |
| occurrences (all) | 0 | 4 | 10 |
| Nasal inflammation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Neonatal respiratory distress | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 8 / 1741 (0.46%) | 12 / 3494 (0.34%) |
| occurrences (all) | 0 | 8 | 12 |
| Neonatal tachypnoea | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 1 | 2 |
| Neonatal respiratory depression | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 3 / 1741 (0.17%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Oropharyngeal pain | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 2 / 1741 (0.11%) | 1 / 3494 (0.03%) |
| occurrences (all) | 2 | 2 | 1 |
| Pharyngeal erythema | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Pneumothorax | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Pulmonary artery stenosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

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| Productive cough | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 1 / 1741 (0.06%) | 5 / 3494 (0.14%) |
| occurrences (all) | 1 | 1 | 6 |
| Pulmonary congestion | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences (all) | 1 | 1 | 2 |
| Pulmonary hypertension | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 3 / 3494 (0.09%) |
| occurrences (all) | 0 | 0 | 3 |
| Respiratory depression | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Respiratory disorder | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 4 / 3557 (0.11%) | 72 / 1741 (4.14%) | 142 / 3494 (4.06%) |
| occurrences (all) | 4 | 164 | 344 |
| Respiratory distress | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Respiratory symptom | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Respiration abnormal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rhinitis allergic | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 1 / 3557 (0.03%) | 7 / 1741 (0.40%) | 21 / 3494 (0.60%) |
| occurrences (all) | 1 | 8 | 23 |
| Rhinorrhoea | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 95 / 1741 (5.46%) | 186 / 3494 (5.32%) |
| occurrences (all) | 1 | 156 | 304 |
| Rhonchi | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Sinonasal obstruction | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 4 / 3494 (0.11%) |
| occurrences (all) | 0 | 1 | 4 |
| Sinus congestion | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 1 | 1 | 1 |
| Sneezing | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 5 / 3494 (0.14%) |
| occurrences (all) | 0 | 0 | 5 |
| Stridor | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 4 / 3494 (0.11%) |
| occurrences (all) | 0 | 0 | 4 |
| Tachypnoea | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 5 / 3494 (0.14%) |
| occurrences (all) | 0 | 2 | 5 |
| Tracheomalacia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |

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| Transient tachypnoea of the newborn alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 8 / 1741 (0.46%) 8 | 13 / 3494 (0.37%) 13 |
| Upper respiratory tract congestion alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 1 / 1741 (0.06%) 1 | 2 / 3494 (0.06%) 2 |
| Vasomotor rhinitis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 7 / 1741 (0.40%) 12 | 11 / 3494 (0.31%) 15 |
| Wheezing alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 19 / 1741 (1.09%) 20 | 28 / 3494 (0.80%) 31 |
| Psychiatric disorders Anxiety alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 3 / 3557 (0.08%) 3 | 0 / 1741 (0.00%) 0 | 0 / 3494 (0.00%) 0 |
| Brief psychotic disorder, with postpartum onset alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 1 / 3557 (0.03%) 1 | 0 / 1741 (0.00%) 0 | 0 / 3494 (0.00%) 0 |
| Initial insomnia alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 1 / 3557 (0.03%) 1 | 0 / 1741 (0.00%) 0 | 0 / 3494 (0.00%) 0 |
| Insomnia alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 3 / 3557 (0.08%) 3 | 0 / 1741 (0.00%) 0 | 0 / 3494 (0.00%) 0 |
| Irritability alternative dictionary used: v26.1 | | | |

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|------------------------------------|------------------|------------------|------------------|
| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 7 / 3494 (0.20%) |
| occurrences (all) | 0 | 2 | 7 |
| Panic attack | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Psychomotor retardation | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Selective eating disorder | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 2 | 2 |
| Sleep disorder | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Tearfulness | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Hepatobiliary disorders | | | |
| Cholelithiasis | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cholestasis of pregnancy | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertransaminasaemia | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |

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|---|------------------|-------------------|-------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Hyperbilirubinaemia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Hyperbilirubinaemia neonatal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 16 / 1741 (0.92%) | 31 / 3494 (0.89%) |
| occurrences (all) | 0 | 16 | 31 |
| Jaundice | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 3 / 3494 (0.09%) |
| occurrences (all) | 0 | 2 | 3 |
| Ocular icterus | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Investigations | | | |
| Acoustic stimulation tests abnormal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 7 / 3494 (0.20%) |
| occurrences (all) | 0 | 1 | 7 |
| Alanine aminotransferase increased | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Apgar score low | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Audiogram abnormal | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood alkaline phosphatase increased alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood bilirubin increased alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Blood glucose decreased alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 4 / 1741 (0.23%) | 4 / 3494 (0.11%) |
| occurrences (all) | 0 | 4 | 4 |
| Blood glucose increased alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Blood iron decreased alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Blood potassium increased alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood pressure increased alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood thyroid stimulating hormone abnormal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

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| Body temperature increased alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Breath sounds abnormal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 1 | 2 |
| C-reactive protein increased alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cardiac murmur alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 11 / 1741 (0.63%) | 38 / 3494 (1.09%) |
| occurrences (all) | 0 | 11 | 38 |
| Cardiac murmur functional alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Coombs direct test positive alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Coombs test positive alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 4 / 3494 (0.11%) |
| occurrences (all) | 0 | 0 | 4 |
| Drug screen positive alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Electroencephalogram normal alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Foetal heart rate decreased | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Haemoglobin decreased | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| HIV test positive | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Heart rate increased | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Head circumference abnormal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 3 / 3494 (0.09%) |
| occurrences (all) | 0 | 1 | 3 |
| Human rhinovirus test positive | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Immunoreactive trypsinogen increased | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Influenza A virus test positive | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
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| Male genital examination abnormal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Medical observation alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Otoacoustic emissions test abnormal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oxygen saturation decreased alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Platelet count decreased alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Respiratory rate increased alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Serum ferritin decreased alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitamin B12 decreased alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| White blood cell count increased alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Weight increased | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Weight decreased | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 5 / 3494 (0.14%) |
| occurrences (all) | 0 | 1 | 5 |
| Injury, poisoning and procedural complications | | | |
| Accidental exposure to product packaging | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Anal injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Animal bite | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 1 | 0 | 2 |
| Animal scratch | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Arthropod bite | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 4 / 1741 (0.23%) | 7 / 3494 (0.20%) |
| occurrences (all) | 0 | 5 | 8 |
| Bone fissure | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|---|------------------|------------------|------------------|
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Burns first degree | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Clavicle fracture | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 6 / 3494 (0.17%) |
| occurrences (all) | 0 | 0 | 6 |
| Chemical burn | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Contusion | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 4 / 1741 (0.23%) | 8 / 3494 (0.23%) |
| occurrences (all) | 1 | 4 | 8 |
| Craniocerebral injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 5 / 1741 (0.29%) | 3 / 3494 (0.09%) |
| occurrences (all) | 0 | 5 | 3 |
| Exposure to communicable disease | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Eye injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Face injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |

| | | | |
|--|------------------|------------------|-------------------|
| Fall | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 3557 (0.08%) | 5 / 1741 (0.29%) | 7 / 3494 (0.20%) |
| occurrences (all) | 3 | 5 | 7 |
| Femur fracture | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 1 | 2 |
| Foetal exposure during pregnancy | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Fracture of clavicle due to birth trauma | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Foreign body ingestion | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Head injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 11 / 3494 (0.31%) |
| occurrences (all) | 0 | 2 | 11 |
| Humerus fracture | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Incision site rash | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Immunisation reaction | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|------------------|------------------|------------------|
| subjects affected / exposed | 1 / 3557 (0.03%) | 1 / 1741 (0.06%) | 3 / 3494 (0.09%) |
| occurrences (all) | 1 | 1 | 3 |
| Injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Joint injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Joint dislocation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Ligament sprain | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Lip injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Limb injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 1 | 2 |
| Mouth injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Muscle strain | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

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|---|------------------|-------------------|-------------------|
| Nasal injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Perineal injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Post vaccination fever | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 12 / 1741 (0.69%) | 18 / 3494 (0.52%) |
| occurrences (all) | 1 | 13 | 24 |
| Procedural complication | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Radial head dislocation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Road traffic accident | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 3557 (0.08%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 3 | 0 | 2 |
| Scar | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin abrasion | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 4 / 3494 (0.11%) |
| occurrences (all) | 0 | 1 | 4 |
| Skin injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|--|------------------|------------------|------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Skin laceration | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 3 / 3494 (0.09%) |
| occurrences (all) | 0 | 1 | 3 |
| Skin wound | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Soft tissue injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Thermal burn | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 1 / 1741 (0.06%) | 3 / 3494 (0.09%) |
| occurrences (all) | 1 | 1 | 3 |
| Ulnar nerve injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vaccination complication | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Congenital, familial and genetic disorders | | | |
| Accessory auricle | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 2 | 1 |
| Albinism | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|--|------------------|-------------------|-------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Ankyloglossia congenital | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 28 / 1741 (1.61%) | 55 / 3494 (1.57%) |
| occurrences (all) | 0 | 28 | 55 |
| Anorectal malformation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Anomaly of external ear congenital | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Atrial septal defect | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 3 / 3494 (0.09%) |
| occurrences (all) | 0 | 1 | 3 |
| Birth mark | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 5 / 3494 (0.14%) |
| occurrences (all) | 0 | 0 | 5 |
| Carnitine-acylcarnitine translocase deficiency | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Cleft uvula | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Congenital syphilis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|--|------------------|-------------------|-------------------|
| Congenital melanosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Congenital musculoskeletal disorder of skull | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Congenital naevus | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 6 / 1741 (0.34%) | 10 / 3494 (0.29%) |
| occurrences (all) | 0 | 6 | 10 |
| Congenital nystagmus | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Congenital skin dimples | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 5 / 1741 (0.29%) | 8 / 3494 (0.23%) |
| occurrences (all) | 0 | 5 | 8 |
| Congenital hypothyroidism | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Congenital thymus absence | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Congenital umbilical hernia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 27 / 1741 (1.55%) | 55 / 3494 (1.57%) |
| occurrences (all) | 0 | 27 | 55 |
| Craniosynostosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dacryostenosis congenital | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Cystic fibrosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Cryptorchism | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 9 / 3494 (0.26%) |
| occurrences (all) | 0 | 0 | 9 |
| Dermoid cyst | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Double heterozygous sickling disorders | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Ear malformation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Fibromatosis colli of infancy | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Haemangioma congenital | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 19 / 3494 (0.54%) |
| occurrences (all) | 0 | 1 | 19 |

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| Glucose-6-phosphate dehydrogenase deficiency | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 3 / 3494 (0.09%) |
| occurrences (all) | 0 | 2 | 3 |
| Heart disease congenital | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Hydrocele | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 8 / 1741 (0.46%) | 13 / 3494 (0.37%) |
| occurrences (all) | 0 | 8 | 13 |
| Laryngomalacia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 3 / 1741 (0.17%) | 7 / 3494 (0.20%) |
| occurrences (all) | 0 | 3 | 7 |
| Labial tie | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 4 / 3494 (0.11%) |
| occurrences (all) | 0 | 1 | 4 |
| Low set ears | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Lymphatic malformation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Naevus flammeus | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 6 / 1741 (0.34%) | 13 / 3494 (0.37%) |
| occurrences (all) | 0 | 6 | 13 |
| Patent ductus arteriosus | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|---|------------------|------------------|------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Phimosi | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 7 / 3494 (0.20%) |
| occurrences (all) | 0 | 2 | 7 |
| Polydactyly | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 2 | 2 |
| Preauricular cyst | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 4 / 3494 (0.11%) |
| occurrences (all) | 0 | 2 | 4 |
| Pulmonary artery stenosis congenital | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Protuberant ear | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Sickle cell anaemia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 3 / 3494 (0.09%) |
| occurrences (all) | 0 | 2 | 3 |
| Sickle cell disease | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Stahl's ear | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |

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| <p>Thalassaemia alpha</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 3557 (0.00%)</p> <p>0</p> | <p>1 / 1741 (0.06%)</p> <p>1</p> | <p>0 / 3494 (0.00%)</p> <p>0</p> |
| <p>Vascular malformation</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 3557 (0.00%)</p> <p>0</p> | <p>0 / 1741 (0.00%)</p> <p>0</p> | <p>1 / 3494 (0.03%)</p> <p>1</p> |
| <p>Ventricular septal defect</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 3557 (0.00%)</p> <p>0</p> | <p>0 / 1741 (0.00%)</p> <p>0</p> | <p>1 / 3494 (0.03%)</p> <p>1</p> |
| <p>Cardiac disorders</p> <p>Bradycardia</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Bradycardia foetal</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Bradycardia neonatal</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Extrasystoles</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Foetal arrhythmia</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Foetal heart rate deceleration abnormality</p> <p>alternative dictionary used: v26.1</p> | <p>0 / 3557 (0.00%)</p> <p>0</p> <p>2 / 3557 (0.06%)</p> <p>2</p> <p>0 / 3557 (0.00%)</p> <p>0</p> <p>1 / 3557 (0.03%)</p> <p>1</p> | <p>1 / 1741 (0.06%)</p> <p>1</p> <p>0 / 1741 (0.00%)</p> <p>0</p> <p>1 / 1741 (0.06%)</p> <p>1</p> <p>0 / 1741 (0.00%)</p> <p>0</p> <p>0 / 1741 (0.00%)</p> <p>0</p> | <p>3 / 3494 (0.09%)</p> <p>3</p> <p>2 / 3494 (0.06%)</p> <p>2</p> <p>1 / 3494 (0.03%)</p> <p>1</p> <p>1 / 3494 (0.03%)</p> <p>1</p> <p>0 / 3494 (0.00%)</p> <p>0</p> |

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| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Left ventricular dilatation | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Mitral valve incompetence | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Neonatal tachycardia | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Palpitations | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tachycardia | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Tachycardia foetal | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 1 | 0 | 1 |
| Ventricular hypertrophy | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Nervous system disorders | | | |
| Agitation neonatal | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |

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|---|------------------|------------------|------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Benign enlargement of the subarachnoid spaces | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Brain oedema | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Burning sensation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Carpal tunnel syndrome | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Cerebral haemorrhage | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Cerebral ventricle dilatation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Dizziness | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 3557 (0.08%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Drooling | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |

| | | | |
|--|---------------------------------------|----------------------------------|----------------------------------|
| <p>Facial paralysis</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 3557 (0.00%)</p> <p>0</p> | <p>0 / 1741 (0.00%)</p> <p>0</p> | <p>1 / 3494 (0.03%)</p> <p>1</p> |
| <p>Febrile convulsion</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 3557 (0.00%)</p> <p>0</p> | <p>3 / 1741 (0.17%)</p> <p>4</p> | <p>1 / 3494 (0.03%)</p> <p>1</p> |
| <p>Fontanelle depressed</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 3557 (0.00%)</p> <p>0</p> | <p>0 / 1741 (0.00%)</p> <p>0</p> | <p>1 / 3494 (0.03%)</p> <p>1</p> |
| <p>Gross motor delay</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 3557 (0.00%)</p> <p>0</p> | <p>0 / 1741 (0.00%)</p> <p>0</p> | <p>1 / 3494 (0.03%)</p> <p>1</p> |
| <p>Haemorrhage intracranial</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 3557 (0.00%)</p> <p>0</p> | <p>0 / 1741 (0.00%)</p> <p>0</p> | <p>1 / 3494 (0.03%)</p> <p>1</p> |
| <p>Headache</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>953 / 3557 (26.79%)</p> <p>963</p> | <p>0 / 1741 (0.00%)</p> <p>0</p> | <p>0 / 3494 (0.00%)</p> <p>0</p> |
| <p>Hypertonia</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 3557 (0.00%)</p> <p>0</p> | <p>2 / 1741 (0.11%)</p> <p>2</p> | <p>9 / 3494 (0.26%)</p> <p>9</p> |
| <p>Hypersomnia</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 3557 (0.00%)</p> <p>0</p> | <p>1 / 1741 (0.06%)</p> <p>1</p> | <p>0 / 3494 (0.00%)</p> <p>0</p> |
| <p>Hypotonia</p> <p>alternative dictionary used: v26.1 26.1</p> | | | |

| | | | |
|---|------------------|------------------|------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 5 / 1741 (0.29%) | 9 / 3494 (0.26%) |
| occurrences (all) | 0 | 5 | 10 |
| Infant irritability | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| IVth nerve paralysis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Lethargy | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 2 | 1 |
| Language disorder | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Migraine | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 3557 (0.08%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Motor developmental delay | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 3 / 3494 (0.09%) |
| occurrences (all) | 0 | 0 | 3 |
| Movement disorder | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Myoclonus | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|------------------|------------------|------------------|
| Nerve compression | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Neurodevelopmental delay | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nystagmus | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 2 | 2 |
| Paraesthesia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Presyncope | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Resting tremor | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Sciatica | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Seizure | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 2 | 2 |
| Seizure like phenomena | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|---|-------------------|-------------------|-------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Subependymal cyst | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Tethered cord syndrome | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Syncope | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Tremor | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Tremor neonatal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 22 / 3557 (0.62%) | 13 / 1741 (0.75%) | 35 / 3494 (1.00%) |
| occurrences (all) | 22 | 13 | 36 |
| Anaemia neonatal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 2 | 1 |
| Anaemia of pregnancy | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|---|------------------|------------------|-------------------|
| subjects affected / exposed | 4 / 3557 (0.11%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Bandaemia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Haemorrhagic disease of newborn | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hypochromic anaemia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 5 / 1741 (0.29%) | 16 / 3494 (0.46%) |
| occurrences (all) | 0 | 5 | 16 |
| Iron deficiency anaemia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 2 / 1741 (0.11%) | 6 / 3494 (0.17%) |
| occurrences (all) | 1 | 2 | 6 |
| Leukopenia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Lymph node pain | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Lymphadenopathy | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 4 / 3557 (0.11%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 4 | 1 | 1 |
| Microcytic anaemia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 5 / 3494 (0.14%) |
| occurrences (all) | 0 | 0 | 5 |

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|--|-----------------------|-----------------------|-----------------------|
| Neutropenia alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 2 / 3494 (0.06%) 2 |
| Polycythaemia alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 2 / 3494 (0.06%) 2 |
| Splenomegaly alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 1 / 3494 (0.03%) 1 |
| Thrombocytopenia alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 1 / 1741 (0.06%) 1 | 2 / 3494 (0.06%) 2 |
| Thrombocytopenia neonatal alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 1 / 1741 (0.06%) 1 | 0 / 3494 (0.00%) 0 |
| Ear and labyrinth disorders Cerumen impaction alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 2 / 3494 (0.06%) 2 |
| Ear discomfort alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 1 / 3494 (0.03%) 1 |
| Ear pain alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 1 / 3557 (0.03%) 1 | 0 / 1741 (0.00%) 0 | 6 / 3494 (0.17%) 7 |
| Eustachian tube dysfunction alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Excessive cerumen production alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Middle ear effusion alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Middle ear inflammation alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Otorrhoea alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 2 | 2 |
| Tympanic membrane disorder alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Tympanic membrane hyperaemia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Vertigo alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Eye disorders Amblyopia alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|------------------|-------------------|-------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Blepharitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Chalazion | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Conjunctival haemorrhage | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 8 / 3494 (0.23%) |
| occurrences (all) | 0 | 2 | 8 |
| Conjunctival hyperaemia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Conjunctivitis allergic | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 1 | 2 |
| Corneal erosion | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dacryostenosis acquired | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 12 / 1741 (0.69%) | 15 / 3494 (0.43%) |
| occurrences (all) | 0 | 13 | 15 |
| Dry eye | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|---|------------------|------------------|------------------|
| Eye discharge | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 8 / 1741 (0.46%) | 5 / 3494 (0.14%) |
| occurrences (all) | 0 | 8 | 5 |
| Eye inflammation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Eye swelling | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 1 | 2 |
| Eyelid ptosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 4 / 3494 (0.11%) |
| occurrences (all) | 0 | 0 | 4 |
| Eyelid skin dryness | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Orbital oedema | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Periorbital oedema | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Strabismus | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 4 / 1741 (0.23%) | 3 / 3494 (0.09%) |
| occurrences (all) | 0 | 4 | 3 |
| Swelling of eyelid | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|---|------------------|------------------|------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Trichiasis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vision blurred | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal distension | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 4 / 1741 (0.23%) | 3 / 3494 (0.09%) |
| occurrences (all) | 0 | 4 | 3 |
| Abdominal discomfort | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 2 / 1741 (0.11%) | 4 / 3494 (0.11%) |
| occurrences (all) | 2 | 2 | 4 |
| Abdominal hernia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Abdominal pain upper | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 4 / 3557 (0.11%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 4 | 1 | 1 |
| Abdominal pain lower | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 7 / 3557 (0.20%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 7 | 0 | 0 |
| Abdominal pain | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|------------------------|-------------------|-------------------|
| subjects affected / exposed | 499 / 3557 (14.03%) | 19 / 1741 (1.09%) | 33 / 3494 (0.94%) |
| occurrences (all) | 500 | 19 | 33 |
| Allergic colitis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Anal eczema alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Anal erythema alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 2 | 1 |
| Anal fissure alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Anal inflammation alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Anal rash alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Aphthous ulcer alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Buccal polyp alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|---|--------------------|-------------------|--------------------|
| Colitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Constipation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 3557 (0.08%) | 31 / 1741 (1.78%) | 73 / 3494 (2.09%) |
| occurrences (all) | 3 | 32 | 75 |
| Constipation neonatal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dental discomfort | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Diarrhoea haemorrhagic | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Diarrhoea | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 354 / 3557 (9.95%) | 54 / 1741 (3.10%) | 117 / 3494 (3.35%) |
| occurrences (all) | 356 | 62 | 137 |
| Dyschezia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 1 | 2 |
| Dyspepsia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 10 / 3557 (0.28%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 10 | 1 | 1 |
| Dysphagia | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|---|------------------|-------------------|-------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Enlarged uvula | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Enteritis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 2 | 2 |
| Enterocolitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Eosinophilic colitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Flatulence | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 11 / 1741 (0.63%) | 16 / 3494 (0.46%) |
| occurrences (all) | 0 | 11 | 17 |
| Food poisoning | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 3 / 3494 (0.09%) |
| occurrences (all) | 0 | 1 | 3 |
| Frequent bowel movements | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Gastritis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences (all) | 2 | 1 | 2 |

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| Gastrointestinal disorder alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 2 |
| Gastrooesophageal reflux disease alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 6 / 3557 (0.17%) | 51 / 1741 (2.93%) | 89 / 3494 (2.55%) |
| occurrences (all) | 6 | 53 | 91 |
| Gastrooesophageal reflux in neonate alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 1 | 2 |
| Gingival blister alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Gingival cyst alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Haematochezia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 3 / 1741 (0.17%) | 5 / 3494 (0.14%) |
| occurrences (all) | 0 | 3 | 5 |
| Haematemesis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Haemorrhoids alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 9 / 3557 (0.25%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 9 | 0 | 0 |
| Haemorrhoids thrombosed alternative dictionary used: v26.1 26.1 | | | |

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|---|------------------|-------------------|-------------------|
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hyperchlorhydria | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infantile colic | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 15 / 1741 (0.86%) | 25 / 3494 (0.72%) |
| occurrences (all) | 0 | 15 | 25 |
| Infant dyschezia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Infantile spitting up | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 3 / 1741 (0.17%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Inguinal hernia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 3 / 1741 (0.17%) | 4 / 3494 (0.11%) |
| occurrences (all) | 0 | 3 | 4 |
| Meconium plug syndrome | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Mouth cyst | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Mouth ulceration | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |

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|---|-------------------------------|-----------------------|-----------------------|
| Nausea alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 603 / 3557 (16.95%) 606 | 1 / 1741 (0.06%) 1 | 1 / 3494 (0.03%) 1 |
| Oesophagitis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 1 / 1741 (0.06%) 1 | 0 / 3494 (0.00%) 0 |
| Oral disorder alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 1 / 3494 (0.03%) 1 |
| Peptic ulcer alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 1 / 3557 (0.03%) 1 | 0 / 1741 (0.00%) 0 | 0 / 3494 (0.00%) 0 |
| Proctitis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 1 / 3494 (0.03%) 1 |
| Regurgitation alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 7 / 1741 (0.40%) 7 | 6 / 3494 (0.17%) 6 |
| Rectal prolapse alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 1 / 3494 (0.03%) 1 |
| Stomatitis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 3 / 1741 (0.17%) 3 | 6 / 3494 (0.17%) 6 |
| Teething alternative dictionary used: v26.1 26.1 | | | |

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|---|--------------------|-------------------|-------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 12 / 1741 (0.69%) | 36 / 3494 (1.03%) |
| occurrences (all) | 0 | 13 | 47 |
| Tooth demineralisation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Tooth development disorder | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Toothache | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 2 | 2 |
| Umbilical hernia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 14 / 1741 (0.80%) | 24 / 3494 (0.69%) |
| occurrences (all) | 0 | 14 | 24 |
| Upper gastrointestinal haemorrhage | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vomiting projectile | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Vomiting | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 285 / 3557 (8.01%) | 32 / 1741 (1.84%) | 57 / 3494 (1.63%) |
| occurrences (all) | 286 | 32 | 60 |
| Skin and subcutaneous tissue disorders | | | |
| Acne infantile | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 3 / 1741 (0.17%) | 13 / 3494 (0.37%) |
| occurrences (all) | 0 | 3 | 13 |
| Alopecia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Blister | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 1 | 2 |
| Cafe au lait spots | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 1 | 2 |
| Cellulite | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Dermatitis allergic | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 5 / 3494 (0.14%) |
| occurrences (all) | 0 | 1 | 5 |
| Decubitus ulcer | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dermatitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 19 / 1741 (1.09%) | 40 / 3494 (1.14%) |
| occurrences (all) | 2 | 19 | 40 |
| Dermal cyst | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 2 | 2 |

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| Dermatitis atopic | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 47 / 1741 (2.70%) | 72 / 3494 (2.06%) |
| occurrences (all) | 0 | 50 | 74 |
| Dermatitis contact | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 5 / 1741 (0.29%) | 12 / 3494 (0.34%) |
| occurrences (all) | 0 | 5 | 12 |
| Dermatitis diaper | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 73 / 1741 (4.19%) | 146 / 3494 (4.18%) |
| occurrences (all) | 0 | 81 | 164 |
| Drug eruption | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Dry skin | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 4 / 1741 (0.23%) | 11 / 3494 (0.31%) |
| occurrences (all) | 0 | 4 | 11 |
| Eczema | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 44 / 1741 (2.53%) | 91 / 3494 (2.60%) |
| occurrences (all) | 1 | 47 | 92 |
| Eczema asteatotic | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Eczema infantile | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 4 / 1741 (0.23%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 4 | 2 |
| Eczema nummular | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Erythema | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 3 / 1741 (0.17%) | 4 / 3494 (0.11%) |
| occurrences (all) | 1 | 4 | 4 |
| Erythema toxicum neonatorum | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 3 / 1741 (0.17%) | 7 / 3494 (0.20%) |
| occurrences (all) | 0 | 3 | 7 |
| Hand dermatitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Herpes gestationis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hyperhidrosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Ingrowing nail | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 5 / 3494 (0.14%) |
| occurrences (all) | 0 | 0 | 5 |
| Intertrigo | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Macule | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 2 | 1 |

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| Melanoderma | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Milia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Miliaria | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 19 / 1741 (1.09%) | 42 / 3494 (1.20%) |
| occurrences (all) | 0 | 19 | 44 |
| Nail fold inflammation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Papule | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Perioral dermatitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Petechiae | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Pigmentation disorder | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Pityriasis alba | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 3 / 3494 (0.09%) |
| occurrences (all) | 0 | 2 | 3 |
| Pityriasis rosea | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Pityriasis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Post inflammatory pigmentation change | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Prurigo | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 2 | 1 |
| Pruritus | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 3557 (0.08%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Rash macular | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Rash maculo-papular | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 4 / 3494 (0.11%) |
| occurrences (all) | 0 | 1 | 4 |
| Rash morbilliform | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

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| Rash erythematous | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Rash | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 34 / 1741 (1.95%) | 82 / 3494 (2.35%) |
| occurrences (all) | 2 | 37 | 84 |
| Rash neonatal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Rash papular | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 8 / 3494 (0.23%) |
| occurrences (all) | 0 | 0 | 8 |
| Rash pruritic | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Seborrhoea | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Seborrhoeic dermatitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 39 / 1741 (2.24%) | 91 / 3494 (2.60%) |
| occurrences (all) | 0 | 39 | 91 |
| Skin hyperpigmentation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin exfoliation | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 3 / 1741 (0.17%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Skin hypopigmentation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 1 | 2 |
| Skin irritation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Skin lesion | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 5 / 3494 (0.14%) |
| occurrences (all) | 0 | 1 | 5 |
| Skin ulcer | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Skin mass | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Solar dermatitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Toxic skin eruption | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 2 | 2 |
| Transient neonatal pustular melanosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |

| | | | |
|---|--|--|--|
| <p>Urticaria</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>3 / 3557 (0.08%)</p> <p>3</p> | <p>3 / 1741 (0.17%)</p> <p>3</p> | <p>7 / 3494 (0.20%)</p> <p>7</p> |
| <p>Umbilical discharge</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 3557 (0.00%)</p> <p>0</p> | <p>1 / 1741 (0.06%)</p> <p>1</p> | <p>0 / 3494 (0.00%)</p> <p>0</p> |
| <p>Umbilical haemorrhage</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 3557 (0.00%)</p> <p>0</p> | <p>0 / 1741 (0.00%)</p> <p>0</p> | <p>1 / 3494 (0.03%)</p> <p>1</p> |
| <p>Urticaria papular</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 3557 (0.00%)</p> <p>0</p> | <p>0 / 1741 (0.00%)</p> <p>0</p> | <p>2 / 3494 (0.06%)</p> <p>2</p> |
| <p>Vitiligo</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 3557 (0.00%)</p> <p>0</p> | <p>0 / 1741 (0.00%)</p> <p>0</p> | <p>1 / 3494 (0.03%)</p> <p>1</p> |
| <p>Renal and urinary disorders</p> <p>Anuria</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Dysuria</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Haematuria</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Hydronephrosis</p> <p>alternative dictionary used: v26.1 26.1</p> | <p>0 / 3557 (0.00%)</p> <p>0</p> <p>1 / 3557 (0.03%)</p> <p>1</p> <p>0 / 3557 (0.00%)</p> <p>0</p> | <p>0 / 1741 (0.00%)</p> <p>0</p> <p>0 / 1741 (0.00%)</p> <p>0</p> <p>0 / 1741 (0.00%)</p> <p>0</p> | <p>1 / 3494 (0.03%)</p> <p>1</p> <p>1 / 3494 (0.03%)</p> <p>1</p> <p>1 / 3494 (0.03%)</p> <p>1</p> |

| | | | |
|---|------------------|------------------|------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 1 | 2 |
| Oliguria | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Pollakiuria | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Proteinuria | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 3557 (0.08%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Pyelocaliectasis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 3 / 3494 (0.09%) |
| occurrences (all) | 0 | 1 | 3 |
| Renal colic | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary hesitation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Vesicoureteric reflux | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Endocrine disorders | | | |
| Hypothyroidism | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|------------------|-------------------|-------------------|
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Precocious puberty | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Thyroid dysfunction in pregnancy | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Transient neonatal hyperthyrotropinaemia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Acquired plagiocephaly | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 15 / 1741 (0.86%) | 30 / 3494 (0.86%) |
| occurrences (all) | 0 | 15 | 30 |
| Arthralgia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Asymmetric gluteal fold | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 2 | 1 |
| Asymmetric thigh fold | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Axillary mass | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|---|-------------------|------------------|------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Back pain | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 15 / 3557 (0.42%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 16 | 0 | 0 |
| Bone disorder | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Bone hypertrophy | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Foot deformity | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 1 | 2 |
| Head deformity | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 4 / 3494 (0.11%) |
| occurrences (all) | 0 | 2 | 4 |
| Hypertonia neonatal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hypotonia neonatal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Joint hyperextension | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |

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| Joint noise | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 4 / 3494 (0.11%) |
| occurrences (all) | 0 | 0 | 4 |
| Joint laxity | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Ligament laxity | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Joint range of motion decreased | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Ligament pain | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Limb asymmetry | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Muscle spasms | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 4 / 3557 (0.11%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 4 | 1 | 0 |
| Muscle twitching | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Muscular weakness | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal chest pain | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Myalgia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 2 | 0 | 1 |
| Musculoskeletal disorder | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Newborn head moulding | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Nose deformity | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Pain in extremity | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Posture abnormal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Pubic pain | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 3557 (0.08%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |

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|--|-----------------------|-------------------------|-------------------------|
| Short stature alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 1 / 1741 (0.06%) 1 | 0 / 3494 (0.00%) 0 |
| Snapping hip syndrome alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 2 / 3494 (0.06%) 2 |
| Soft tissue mass alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 1 / 1741 (0.06%) 1 | 0 / 3494 (0.00%) 0 |
| Tendon disorder alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 1 / 1741 (0.06%) 1 | 0 / 3494 (0.00%) 0 |
| Torticollis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 2 / 1741 (0.11%) 2 | 10 / 3494 (0.29%) 10 |
| Infections and infestations Abscess alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 1 / 1741 (0.06%) 1 | 0 / 3494 (0.00%) 0 |
| Abscess limb alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 1 / 3557 (0.03%) 1 | 1 / 1741 (0.06%) 1 | 4 / 3494 (0.11%) 4 |
| Acarodermatitis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 1 / 3557 (0.03%) 1 | 14 / 1741 (0.80%) 16 | 31 / 3494 (0.89%) 39 |
| Acute sinusitis alternative dictionary used: v26.1 26.1 | | | |

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|---|------------------|------------------|------------------|
| subjects affected / exposed | 2 / 3557 (0.06%) | 4 / 1741 (0.23%) | 5 / 3494 (0.14%) |
| occurrences (all) | 2 | 4 | 6 |
| Adenoviral upper respiratory infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Adenovirus infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 4 / 3494 (0.11%) |
| occurrences (all) | 0 | 2 | 4 |
| Amniotic cavity infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Amoebic dysentery | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 2 | 3 |
| Anal candidiasis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Anal abscess | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Ascariasis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Asymptomatic bacteriuria | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 2 | 0 | 1 |

| | | | |
|---|------------------|--------------------|--------------------|
| Balanitis candida | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Bartholin's abscess | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Beta haemolytic streptococcal infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Bacterial disease carrier | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 4 / 3557 (0.11%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Bacterial vaginosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 7 / 3557 (0.20%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 7 | 0 | 0 |
| Body tinea | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 7 / 1741 (0.40%) | 8 / 3494 (0.23%) |
| occurrences (all) | 0 | 7 | 8 |
| Breast abscess | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Bronchiolitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 152 / 1741 (8.73%) | 298 / 3494 (8.53%) |
| occurrences (all) | 0 | 176 | 387 |
| Bronchitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|---|-------------------|--------------------|--------------------|
| subjects affected / exposed | 1 / 3557 (0.03%) | 39 / 1741 (2.24%) | 82 / 3494 (2.35%) |
| occurrences (all) | 1 | 44 | 98 |
| COVID-19 | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 54 / 3557 (1.52%) | 130 / 1741 (7.47%) | 259 / 3494 (7.41%) |
| occurrences (all) | 54 | 132 | 263 |
| Burkholderia mallei infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Bullous impetigo | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 2 | 1 |
| Candida infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 13 / 1741 (0.75%) | 17 / 3494 (0.49%) |
| occurrences (all) | 1 | 14 | 19 |
| Candida nappy rash | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 11 / 3494 (0.31%) |
| occurrences (all) | 0 | 2 | 12 |
| Cellulitis orbital | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Cellulitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Clostridium difficile infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |

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|--|-----------------------|-------------------------|---------------------------|
| Conjunctivitis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 2 / 3557 (0.06%) 2 | 63 / 1741 (3.62%) 73 | 153 / 3494 (4.38%) 171 |
| Conjunctivitis viral alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 3 / 1741 (0.17%) 3 | 6 / 3494 (0.17%) 6 |
| Conjunctivitis bacterial alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 6 / 1741 (0.34%) 6 | 11 / 3494 (0.31%) 11 |
| Croup infectious alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 12 / 1741 (0.69%) 13 | 24 / 3494 (0.69%) 29 |
| Cystitis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 1 / 3557 (0.03%) 1 | 0 / 1741 (0.00%) 0 | 0 / 3494 (0.00%) 0 |
| Dacryocystitis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 2 / 1741 (0.11%) 2 | 3 / 3494 (0.09%) 3 |
| Dengue fever alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 1 / 3494 (0.03%) 1 |
| Dermatitis infected alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 2 / 3494 (0.06%) 3 |
| Dermatophytosis of nail alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|------------------|-------------------|--------------------|
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Diarrhoea infectious | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dysentery | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 1 | 2 |
| Ear infection viral | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Ear infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 63 / 1741 (3.62%) | 122 / 3494 (3.49%) |
| occurrences (all) | 2 | 86 | 151 |
| Eczema impetiginous | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Enterovirus infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 3 / 1741 (0.17%) | 4 / 3494 (0.11%) |
| occurrences (all) | 0 | 3 | 4 |
| Enterobiasis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Eczema infected | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |

| | | | |
|---|------------------|-------------------|-------------------|
| Erysipelas | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Erythema infectiosum | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Escherichia urinary tract infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Exanthema subitum | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 12 / 1741 (0.69%) | 23 / 3494 (0.66%) |
| occurrences (all) | 0 | 12 | 23 |
| Escherichia infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 8 / 3494 (0.23%) |
| occurrences (all) | 0 | 1 | 8 |
| Eye infection staphylococcal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Eye infection viral | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Eyelid infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|------------------|-------------------|-------------------|
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Folliculitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Fungal infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 3 / 1741 (0.17%) | 3 / 3494 (0.09%) |
| occurrences (all) | 1 | 3 | 3 |
| Fungal skin infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 10 / 1741 (0.57%) | 16 / 3494 (0.46%) |
| occurrences (all) | 0 | 11 | 16 |
| Furuncle | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 2 | 2 |
| Gastrointestinal viral infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 3 / 3494 (0.09%) |
| occurrences (all) | 0 | 0 | 3 |
| Gastroenteritis adenovirus | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Gastroenteritis bacterial | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Gastroenteritis norovirus | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|-----------------------|-------------------------|---------------------------|
| Gastroenteritis viral alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 3 / 3557 (0.08%) 3 | 5 / 1741 (0.29%) 5 | 17 / 3494 (0.49%) 19 |
| Gastrointestinal infection alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 1 / 1741 (0.06%) 1 | 0 / 3494 (0.00%) 0 |
| Gastroenteritis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 6 / 3557 (0.17%) 6 | 75 / 1741 (4.31%) 90 | 118 / 3494 (3.38%) 143 |
| Genital candidiasis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 3 / 3494 (0.09%) 3 |
| Genital herpes alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 0 / 3494 (0.00%) 0 |
| Groin infection alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 1 / 1741 (0.06%) 1 | 0 / 3494 (0.00%) 0 |
| Groin abscess alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 1 / 3557 (0.03%) 1 | 0 / 1741 (0.00%) 0 | 0 / 3494 (0.00%) 0 |
| Hand-foot-and-mouth disease alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 1 / 3557 (0.03%) 1 | 17 / 1741 (0.98%) 17 | 48 / 3494 (1.37%) 49 |
| Herpangina alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|------------------|-------------------|-------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 7 / 3494 (0.20%) |
| occurrences (all) | 0 | 1 | 7 |
| Herpes simplex | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Herpes virus infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Herpes zoster | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Hordeolum | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Human herpesvirus 6 infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Impetigo | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 13 / 1741 (0.75%) | 29 / 3494 (0.83%) |
| occurrences (all) | 0 | 13 | 29 |
| Infected bite | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Influenza | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 4 / 3557 (0.11%) | 15 / 1741 (0.86%) | 26 / 3494 (0.74%) |
| occurrences (all) | 4 | 15 | 26 |

| | | | |
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| Infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Laryngotracheitis obstructive | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Klebsiella urinary tract infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Labyrinthitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Laryngitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 17 / 1741 (0.98%) | 48 / 3494 (1.37%) |
| occurrences (all) | 0 | 18 | 55 |
| Localised infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Lower respiratory tract infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 63 / 1741 (3.62%) | 130 / 3494 (3.72%) |
| occurrences (all) | 1 | 76 | 150 |
| Lower respiratory tract infection viral | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 7 / 1741 (0.40%) | 8 / 3494 (0.23%) |
| occurrences (all) | 0 | 7 | 8 |
| Mastitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|---|-------------------|------------------------|------------------------|
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Metapneumovirus bronchiolitis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Metapneumovirus infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 3 / 3494 (0.09%) |
| occurrences (all) | 0 | 0 | 3 |
| Nail bed infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Myringitis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Neonatal infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Nasopharyngitis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 17 / 3557 (0.48%) | 339 / 1741 (19.47%) | 666 / 3494 (19.06%) |
| occurrences (all) | 17 | 724 | 1435 |
| Neonatal pneumonia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Norovirus infection alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |

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| Oral viral infection alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 1 / 3494 (0.03%) 1 |
| Ophthalmia neonatorum alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 2 / 1741 (0.11%) 2 | 6 / 3494 (0.17%) 6 |
| Oral candidiasis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 33 / 1741 (1.90%) 37 | 58 / 3494 (1.66%) 65 |
| Oral fungal infection alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 1 / 1741 (0.06%) 1 | 3 / 3494 (0.09%) 3 |
| Oral herpes alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 3 / 3557 (0.08%) 3 | 2 / 1741 (0.11%) 2 | 2 / 3494 (0.06%) 2 |
| Omphalitis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 4 / 1741 (0.23%) 4 | 4 / 3494 (0.11%) 4 |
| Otitis externa alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 1 / 3557 (0.03%) 1 | 0 / 1741 (0.00%) 0 | 4 / 3494 (0.11%) 4 |
| Otitis externa fungal alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 1 / 1741 (0.06%) 1 | 0 / 3494 (0.00%) 0 |
| Otitis media alternative dictionary used: v26.1 26.1 | | | |

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| subjects affected / exposed | 0 / 3557 (0.00%) | 59 / 1741 (3.39%) | 117 / 3494 (3.35%) |
| occurrences (all) | 0 | 80 | 145 |
| Otitis media acute | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 45 / 1741 (2.58%) | 99 / 3494 (2.83%) |
| occurrences (all) | 0 | 55 | 115 |
| Otitis media chronic | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 2 | 1 |
| Parasitic gastroenteritis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Paronychia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 4 / 3494 (0.11%) |
| occurrences (all) | 0 | 1 | 4 |
| Parainfluenzae virus infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 5 / 3494 (0.14%) |
| occurrences (all) | 0 | 1 | 5 |
| Periodontitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pharyngitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 3557 (0.08%) | 15 / 1741 (0.86%) | 41 / 3494 (1.17%) |
| occurrences (all) | 3 | 15 | 42 |
| Pharyngitis streptococcal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 2 | 1 |

| | | | |
|---|------------------|-------------------|-------------------|
| Pharyngotonsillitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 4 / 1741 (0.23%) | 9 / 3494 (0.26%) |
| occurrences (all) | 0 | 4 | 10 |
| Pertussis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Pneumonia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 10 / 1741 (0.57%) | 31 / 3494 (0.89%) |
| occurrences (all) | 0 | 10 | 31 |
| Pneumonia bacterial | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Pneumonia mycoplasmal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Pneumonia respiratory syncytial viral | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Pneumonia viral | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Post procedural cellulitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Pyoderma | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|---|-------------------|-------------------|--------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 3 / 1741 (0.17%) | 6 / 3494 (0.17%) |
| occurrences (all) | 0 | 4 | 8 |
| Pustule | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Respiratory syncytial virus bronchiolitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 25 / 1741 (1.44%) | 22 / 3494 (0.63%) |
| occurrences (all) | 0 | 25 | 23 |
| Respiratory syncytial virus bronchitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 4 / 1741 (0.23%) | 4 / 3494 (0.11%) |
| occurrences (all) | 0 | 4 | 4 |
| Respiratory syncytial virus infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 18 / 1741 (1.03%) | 34 / 3494 (0.97%) |
| occurrences (all) | 0 | 18 | 34 |
| Respiratory tract infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 24 / 3557 (0.67%) | 70 / 1741 (4.02%) | 151 / 3494 (4.32%) |
| occurrences (all) | 24 | 138 | 262 |
| Respiratory tract infection viral | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 6 / 1741 (0.34%) | 4 / 3494 (0.11%) |
| occurrences (all) | 0 | 7 | 4 |
| Rhinitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 76 / 1741 (4.37%) | 154 / 3494 (4.41%) |
| occurrences (all) | 0 | 102 | 203 |
| Rhinovirus infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 3 / 1741 (0.17%) | 10 / 3494 (0.29%) |
| occurrences (all) | 0 | 3 | 12 |

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| Roseola | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Scarlet fever | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Sepsis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Sepsis neonatal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Sinusitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 6 / 3557 (0.17%) | 6 / 1741 (0.34%) | 10 / 3494 (0.29%) |
| occurrences (all) | 6 | 8 | 10 |
| Skin candida | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 8 / 1741 (0.46%) | 4 / 3494 (0.11%) |
| occurrences (all) | 0 | 8 | 4 |
| Skin infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 5 / 3494 (0.14%) |
| occurrences (all) | 0 | 1 | 5 |
| Subcutaneous abscess | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 5 / 3494 (0.14%) |
| occurrences (all) | 0 | 5 | 5 |
| Subglottic laryngitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|------------------|-------------------|--------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Suspected COVID-19 | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 5 / 3557 (0.14%) | 57 / 1741 (3.27%) | 147 / 3494 (4.21%) |
| occurrences (all) | 5 | 58 | 151 |
| Staphylococcal infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Systemic viral infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 3 / 1741 (0.17%) | 6 / 3494 (0.17%) |
| occurrences (all) | 0 | 4 | 6 |
| Toxoplasmosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Thyroglossal cyst infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Tinea capitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 1 | 2 |
| Tinea infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 7 / 3494 (0.20%) |
| occurrences (all) | 0 | 2 | 7 |
| Tinea pedis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |

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|--|-------------------------|-------------------------------|--------------------------------|
| Tinea versicolour alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 3 / 1741 (0.17%) 3 | 4 / 3494 (0.11%) 4 |
| Tonsillitis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 8 / 1741 (0.46%) 8 | 15 / 3494 (0.43%) 15 |
| Tracheitis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 1 / 1741 (0.06%) 1 | 1 / 3494 (0.03%) 1 |
| Tracheobronchitis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 2 / 3494 (0.06%) 2 |
| Upper respiratory tract infection alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 38 / 3557 (1.07%) 40 | 437 / 1741 (25.10%) 861 | 932 / 3494 (26.67%) 1888 |
| Upper respiratory tract infection bacterial alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 2 / 3494 (0.06%) 2 |
| Urinary tract infection alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 61 / 3557 (1.71%) 61 | 9 / 1741 (0.52%) 9 | 30 / 3494 (0.86%) 33 |
| Urogenital infection fungal alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) 0 | 0 / 1741 (0.00%) 0 | 1 / 3494 (0.03%) 1 |
| Vaccination site abscess alternative dictionary used: v26.1 26.1 | | | |

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|---|------------------|-------------------|-------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 1 | 1 |
| Vaginal infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 6 / 3557 (0.17%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 6 | 0 | 1 |
| Varicella | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 6 / 1741 (0.34%) | 13 / 3494 (0.37%) |
| occurrences (all) | 0 | 6 | 13 |
| Viral upper respiratory tract infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 3557 (0.06%) | 27 / 1741 (1.55%) | 47 / 3494 (1.35%) |
| occurrences (all) | 2 | 43 | 66 |
| Viral diarrhoea | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Viral infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 13 / 1741 (0.75%) | 41 / 3494 (1.17%) |
| occurrences (all) | 0 | 13 | 42 |
| Viral pharyngitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 0 | 2 |
| Viral rash | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 13 / 1741 (0.75%) | 24 / 3494 (0.69%) |
| occurrences (all) | 0 | 13 | 24 |
| Viral rhinitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

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| Viral tonsillitis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| | 0 | 0 | 0 |
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| Vulvovaginal candidiasis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 3 / 3557 (0.08%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| | 3 | 1 | 0 |
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| Vulvitis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| | 0 | 0 | 0 |
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| Vulvovaginal mycotic infection alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 4 / 3557 (0.11%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| | 4 | 0 | 0 |
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| Wound infection alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| | 0 | 1 | 0 |
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| Metabolism and nutrition disorders Abnormal loss of weight alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) Breast milk substitute intolerance alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) Cachexia alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) Dairy intolerance alternative dictionary used: v26.1 26.1 | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| | 0 | 1 | 0 |
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| subjects affected / exposed | 0 / 3557 (0.00%) | 5 / 1741 (0.29%) | 3 / 3494 (0.09%) |
| occurrences (all) | 0 | 5 | 3 |
| Decreased appetite | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 3 / 1741 (0.17%) | 3 / 3494 (0.09%) |
| occurrences (all) | 1 | 3 | 3 |
| Dehydration | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 5 / 3494 (0.14%) |
| occurrences (all) | 1 | 0 | 5 |
| Failure to thrive | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 3 / 1741 (0.17%) | 5 / 3494 (0.14%) |
| occurrences (all) | 0 | 3 | 5 |
| Fluid retention | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Food intolerance | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Hyperglycaemia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypervitaminosis D | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hypokalaemia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

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| Hypoglycaemia neonatal alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 4 / 1741 (0.23%) | 3 / 3494 (0.09%) |
| occurrences (all) | 0 | 4 | 3 |
| Hypoglycaemia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 11 / 1741 (0.63%) | 20 / 3494 (0.57%) |
| occurrences (all) | 1 | 11 | 20 |
| Hypocalcaemia alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Iron deficiency alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 4 / 3557 (0.11%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 4 | 0 | 1 |
| Lactose intolerance alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 2 / 3494 (0.06%) |
| occurrences (all) | 0 | 2 | 2 |
| Malnutrition alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 3 / 3494 (0.09%) |
| occurrences (all) | 0 | 1 | 3 |
| Metabolic acidosis alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Metabolic disorder alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 1 / 1741 (0.06%) | 0 / 3494 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Milk soy protein intolerance alternative dictionary used: v26.1 26.1 | | | |

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|---|------------------|------------------|-------------------|
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Obesity | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 4 / 1741 (0.23%) | 1 / 3494 (0.03%) |
| occurrences (all) | 1 | 4 | 1 |
| Overweight | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 4 / 1741 (0.23%) | 10 / 3494 (0.29%) |
| occurrences (all) | 0 | 4 | 10 |
| Poor feeding infant | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 3 / 1741 (0.17%) | 12 / 3494 (0.34%) |
| occurrences (all) | 0 | 4 | 13 |
| Underweight | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 7 / 1741 (0.40%) | 4 / 3494 (0.11%) |
| occurrences (all) | 1 | 7 | 4 |
| Vitamin B12 deficiency | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 3557 (0.03%) | 0 / 1741 (0.00%) | 0 / 3494 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vitamin D deficiency | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Vitamin K deficiency | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 0 / 1741 (0.00%) | 1 / 3494 (0.03%) |
| occurrences (all) | 0 | 0 | 1 |
| Weight gain poor | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 3557 (0.00%) | 2 / 1741 (0.11%) | 7 / 3494 (0.20%) |
| occurrences (all) | 0 | 2 | 7 |

| Non-serious adverse events | Placebo Group - Mother | | |
|---|---------------------------|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 1011 / 1771 (57.09%) | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Acrochordon | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Anogenital warts | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Haemangioma of skin | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Haemangioma | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Infantile haemangioma | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lipoma | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Melanocytic naevus | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ocular neoplasm | | | |
| alternative dictionary used: v26.1 | | | |

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|------------------------------------|------------------|--|--|
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pyogenic granuloma | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin papilloma | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ulcerated haemangioma | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Xanthogranuloma | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vascular disorders | | | |
| Angiopathy | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cyanosis | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Haematoma | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hot flush | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |

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| <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Hypertension</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>1 / 1771 (0.06%)</p> <p>occurrences (all)</p> <p>1</p> <p>Hypotension</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>1 / 1771 (0.06%)</p> <p>occurrences (all)</p> <p>1</p> <p>Varicose vein</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Vasodilatation</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | | |
| <p>Surgical and medical procedures</p> <p>Medically induced preterm birth</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>1 / 1771 (0.06%)</p> <p>occurrences (all)</p> <p>1</p> | | | |
| <p>Pregnancy, puerperium and perinatal conditions</p> <p>Birth trauma</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Breech presentation</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Caput succedaneum</p> <p>alternative dictionary used: v26.1 26.1</p> | | | |

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|--|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cephalhaematoma | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cephalo-pelvic disproportion | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Complication of delivery | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Complication of pregnancy | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 5 / 1771 (0.28%) | | |
| occurrences (all) | 5 | | |
| False labour | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 1771 (0.17%) | | |
| occurrences (all) | 3 | | |
| Foetal acidosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Foetal distress syndrome | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Foetal growth restriction | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 4 / 1771 (0.23%) | | |
| occurrences (all) | 4 | | |

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| Foetal hypokinesia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Foetal macrosomia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Foetal malpresentation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gestational diabetes | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 18 / 1771 (1.02%) | | |
| occurrences (all) | 18 | | |
| Gestational hypertension | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 6 / 1771 (0.34%) | | |
| occurrences (all) | 6 | | |
| Haemorrhage in pregnancy | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Hypothermia neonatal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Jaundice neonatal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Large for dates baby | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Low birth weight baby | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Meconium stain | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Maternal condition affecting foetus | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Meconium in amniotic fluid | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Morning sickness | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | |
| occurrences (all) | 2 | | |
| Neonatal disorder | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Oligohydramnios | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | |
| occurrences (all) | 2 | | |
| Omphalorrhexis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|---|------------------|--|--|
| Placenta praevia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Placental disorder | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Premature rupture of membranes | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Poor weight gain neonatal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Postpartum haemorrhage | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pre-eclampsia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | |
| occurrences (all) | 2 | | |
| Premature baby | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Premature labour | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 8 / 1771 (0.45%) | | |
| occurrences (all) | 8 | | |
| Polyhydramnios | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|------------------|--|--|
| subjects affected / exposed | 2 / 1771 (0.11%) | | |
| occurrences (all) | 2 | | |
| Prolonged labour | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Preterm premature rupture of membranes | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | |
| occurrences (all) | 2 | | |
| Retained placenta or membranes | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Shoulder dystocia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Small for dates baby | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Threatened labour | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Umbilical cord around neck | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Umbilical cord abnormality | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|---|--|--|--|
| <p>Umbilical granuloma</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 1771 (0.00%)</p> <p>0</p> | | |
| <p>Umbilical cord haemorrhage</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 1771 (0.00%)</p> <p>0</p> | | |
| <p>Uterine hypotonus</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 1771 (0.00%)</p> <p>0</p> | | |
| <p>Uterine irritability</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 1771 (0.00%)</p> <p>0</p> | | |
| <p>Uterine contractions during pregnancy</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>6 / 1771 (0.34%)</p> <p>7</p> | | |
| <p>Weight decrease neonatal</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 1771 (0.00%)</p> <p>0</p> | | |
| <p>General disorders and administration site conditions</p> <p>Administration site erythema</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Administration site pain</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>8 / 1771 (0.45%)</p> <p>8</p> <p>231 / 1771 (13.04%)</p> <p>231</p> | | |
| Administration site swelling | | | |

| | | | |
|--|------------------|--|--|
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 8 / 1771 (0.45%) | | |
| occurrences (all) | 8 | | |
| Adverse food reaction | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Asthenia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 1771 (0.17%) | | |
| occurrences (all) | 3 | | |
| Chills | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Crepitations | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Crying | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cyst | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Developmental delay | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Discomfort | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|--|------------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Feeling hot | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Feeling jittery | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Fever neonatal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Fatigue | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 479 / 1771 (27.05%) | | |
| occurrences (all) | 480 | | |
| High-pitched crying | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypertrophy | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hyperthermia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypothermia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | | |
|------------------------------------|------------------|--|--|--|
| Illness | | | | |
| alternative dictionary used: v26.1 | | | | |
| 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Ill-defined disorder | | | | |
| alternative dictionary used: v26.1 | | | | |
| 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Injection site swelling | | | | |
| alternative dictionary used: v26.1 | | | | |
| 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Injection site pruritus | | | | |
| alternative dictionary used: v26.1 | | | | |
| 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences (all) | 1 | | | |
| Injection site pain | | | | |
| alternative dictionary used: v26.1 | | | | |
| 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences (all) | 1 | | | |
| Injection site oedema | | | | |
| alternative dictionary used: v26.1 | | | | |
| 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Injection site erythema | | | | |
| alternative dictionary used: v26.1 | | | | |
| 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Injection site bruising | | | | |
| alternative dictionary used: v26.1 | | | | |
| 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences (all) | 1 | | | |
| Influenza like illness | | | | |
| alternative dictionary used: v26.1 | | | | |
| 26.1 | | | | |

| | | | |
|---|------------------|--|--|
| subjects affected / exposed | 2 / 1771 (0.11%) | | |
| occurrences (all) | 2 | | |
| Irritability postvaccinal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Injury associated with device | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Macrosomia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Malaise | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Oedema | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Oedema peripheral | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 4 / 1771 (0.23%) | | |
| occurrences (all) | 4 | | |
| Pain | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Peripheral swelling | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |

| | | | |
|---|------------------|--|--|
| Puncture site pain | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pyrexia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 9 / 1771 (0.51%) | | |
| occurrences (all) | 9 | | |
| Swelling | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Swelling face | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Thirst | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vaccination site induration | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vaccination site pain | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | |
| occurrences (all) | 2 | | |
| Vessel puncture site bruise | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vessel puncture site pain | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Immune system disorders | | | |
| ABO incompatibility | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Allergy to arthropod bite | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Allergy to arthropod sting | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Allergy to chemicals | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Allergy to vaccine | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Alloimmunisation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Atopy | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Drug hypersensitivity | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|--|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Food allergy | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypersensitivity | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Milk allergy | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Multiple allergies | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nutritional supplement allergy | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rhesus incompatibility | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Seasonal allergy | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Reproductive system and breast disorders | | | |
| Acquired phimosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Adnexa uteri cyst | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Balanoposthitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bilateral breast buds | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Coital bleeding | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Galactostasis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Genital blister | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Genital discomfort | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Genital labial adhesions | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

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|---|------------------|--|--|
| Genital macule | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Genital prolapse | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Genital ulceration | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Gynaecomastia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ovarian cyst | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Penile adhesion | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pelvic pain | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Pruritus genital | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | |
| occurrences (all) | 2 | | |
| Scrotal swelling | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Testicular retraction | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vaginal discharge | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 1771 (0.17%) | | |
| occurrences (all) | 3 | | |
| Vaginal disorder | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Vaginal haemorrhage | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vulvovaginal erythema | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vulval oedema | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vulvovaginal pain | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vulvovaginal pruritus | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|---|------------------|--|--|
| Respiratory, thoracic and mediastinal disorders | | | |
| Adenoidal hypertrophy | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Apnoea | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Apnoeic attack | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Asthma | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Atelectasis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Asthmatic crisis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Brief resolved unexplained event | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bronchial hyperreactivity | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bronchial obstruction | | | |
| alternative dictionary used: v26.1 | | | |

| | | | |
|------------------------------------|------------------|--|--|
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bronchiolitis obliterans syndrome | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bronchitis chronic | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bronchospasm | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Catarrh | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Choking | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Childhood asthma | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cough | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 3 / 1771 (0.17%) | | |
| occurrences (all) | 3 | | |
| Dyspnoea | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |

| | | | |
|--|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dysphonia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Epistaxis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hyperventilation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypoxia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Infantile apnoea | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Increased bronchial secretion | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lower respiratory tract congestion | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Meconium aspiration syndrome | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

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|---|------------------|--|--|
| Nasal congestion | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Nasal discomfort | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nasal disorder | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nasal dryness | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nasal obstruction | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nasal inflammation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Neonatal respiratory distress | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Neonatal tachypnoea | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Neonatal respiratory depression | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|--|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Oropharyngeal pain | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | |
| occurrences (all) | 2 | | |
| Pharyngeal erythema | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pneumothorax | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pulmonary artery stenosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Productive cough | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | |
| occurrences (all) | 2 | | |
| Pulmonary congestion | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pulmonary hypertension | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Respiratory depression | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

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|---|------------------|--|--|
| Respiratory disorder | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 1771 (0.17%) | | |
| occurrences (all) | 3 | | |
| Respiratory distress | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Respiratory symptom | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Respiration abnormal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rhinitis allergic | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 1771 (0.17%) | | |
| occurrences (all) | 3 | | |
| Rhinorrhoea | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Rhonchi | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sinonasal obstruction | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sinus congestion | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|---|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sneezing | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Stridor | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tachypnoea | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tracheomalacia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Transient tachypnoea of the newborn | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Upper respiratory tract congestion | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vasomotor rhinitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Wheezing | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

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|---|------------------|--|--|
| Psychiatric disorders | | | |
| Anxiety | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Brief psychotic disorder, with postpartum onset | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Initial insomnia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Insomnia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Irritability | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Panic attack | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Psychomotor retardation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Selective eating disorder | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sleep disorder | | | |
| alternative dictionary used: v26.1 | | | |

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|------------------------------------|------------------|--|--|
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tearfulness | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hepatobiliary disorders | | | |
| Cholelithiasis | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cholestasis of pregnancy | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 4 / 1771 (0.23%) | | |
| occurrences (all) | 4 | | |
| Hypertransaminaemia | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hyperbilirubinaemia | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hyperbilirubinaemia neonatal | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Jaundice | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ocular icterus | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |

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|--------------------------------------|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Investigations | | | |
| Acoustic stimulation tests abnormal | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Alanine aminotransferase increased | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Apgar score low | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Audiogram abnormal | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood alkaline phosphatase increased | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood bilirubin increased | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood glucose decreased | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood glucose increased | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |

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|--|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood iron decreased | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Blood potassium increased | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood pressure increased | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | |
| occurrences (all) | 2 | | |
| Blood thyroid stimulating hormone abnormal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Body temperature increased | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Breath sounds abnormal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| C-reactive protein increased | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cardiac murmur | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

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|---|-----------------------|--|--|
| Cardiac murmur functional alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Coombs direct test positive alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Coombs test positive alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Drug screen positive alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Electroencephalogram normal alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Foetal heart rate decreased alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Haemoglobin decreased alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| HIV test positive alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 1 / 1771 (0.06%) 1 | | |
| Heart rate increased alternative dictionary used: v26.1 26.1 | | | |

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|---|------------------|--|--|
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Head circumference abnormal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Human rhinovirus test positive | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Immunoreactive trypsinogen increased | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Influenza A virus test positive | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Male genital examination abnormal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Medical observation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Otoacoustic emissions test abnormal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Oxygen saturation decreased | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

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|--|-----------------------|--|--|
| Platelet count decreased alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Respiratory rate increased alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Serum ferritin decreased alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 1 / 1771 (0.06%) 1 | | |
| Vitamin B12 decreased alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| White blood cell count increased alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Weight increased alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 1 / 1771 (0.06%) 1 | | |
| Weight decreased alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Injury, poisoning and procedural complications Accidental exposure to product packaging alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Anal injury | | | |

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|--|------------------|--|--|
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Animal bite | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Animal scratch | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Arthropod bite | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bone fissure | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Burns first degree | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Clavicle fracture | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Chemical burn | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Contusion | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|--|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Craniocerebral injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Exposure to communicable disease | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eye injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Face injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Fall | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Femur fracture | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Foetal exposure during pregnancy | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Fracture of clavicle due to birth trauma | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

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|---|------------------|--|--|
| Foreign body ingestion | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Head injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Humerus fracture | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Incision site rash | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Immunisation reaction | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Joint injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Joint dislocation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ligament sprain | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|--|------------------|--|--|
| subjects affected / exposed | 2 / 1771 (0.11%) | | |
| occurrences (all) | 2 | | |
| Lip injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Limb injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Mouth injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Muscle strain | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Nasal injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Perineal injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Post vaccination fever | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Procedural complication | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|--|------------------|--|--|
| Radial head dislocation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Road traffic accident | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Scar | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin abrasion | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin laceration | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin wound | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Soft tissue injury | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Thermal burn | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|--|--|--|
| <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Ulnar nerve injury</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Vaccination complication</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | | |
| <p>Congenital, familial and genetic disorders</p> <p>Accessory auricle</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Albinism</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Ankyloglossia congenital</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Anorectal malformation</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Anomaly of external ear congenital</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Atrial septal defect</p> <p>alternative dictionary used: v26.1 26.1</p> | | | |

| | | | |
|---|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Birth mark | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Carnitine-acylcarnitine translocase deficiency | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cleft uvula | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Congenital syphilis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Congenital melanosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Congenital musculoskeletal disorder of skull | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Congenital naevus | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Congenital nystagmus | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|---|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Congenital skin dimples | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Congenital hypothyroidism | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Congenital thymus absence | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Congenital umbilical hernia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Craniosynostosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dacryostenosis congenital | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cystic fibrosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cryptorchism | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

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|--|------------------|--|--|
| Dermoid cyst | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Double heterozygous sickling disorders | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ear malformation | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Fibromatosis colli of infancy | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Haemangioma congenital | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Glucose-6-phosphate dehydrogenase deficiency | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Heart disease congenital | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hydrocele | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Laryngomalacia | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |

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|---|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Labial tie | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Low set ears | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lymphatic malformation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Naevus flammeus | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Patent ductus arteriosus | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Phimosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Polydactyly | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Preauricular cyst | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

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|--|-----------------------|--|--|
| Pulmonary artery stenosis congenital alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Protuberant ear alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Sickle cell anaemia alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Sickle cell disease alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Stahl's ear alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Thalassaemia alpha alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Vascular malformation alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Ventricular septal defect alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Cardiac disorders | | | |

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|--|------------------|--|--|
| Bradycardia | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bradycardia foetal | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Bradycardia neonatal | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Extrasystoles | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Foetal arrhythmia | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Foetal heart rate deceleration abnormality | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Left ventricular dilatation | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Mitral valve incompetence | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Neonatal tachycardia | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |

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|--|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Palpitations | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | |
| occurrences (all) | 2 | | |
| Tachycardia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tachycardia foetal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ventricular hypertrophy | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nervous system disorders | | | |
| Agitation neonatal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Benign enlargement of the subarachnoid spaces | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Brain oedema | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Burning sensation | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|---|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Carpal tunnel syndrome | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | |
| occurrences (all) | 2 | | |
| Cerebral haemorrhage | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cerebral ventricle dilatation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dizziness | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | |
| occurrences (all) | 2 | | |
| Drooling | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Facial paralysis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Febrile convulsion | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Fontanelle depressed | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

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|--|-------------------------------|--|--|
| Gross motor delay alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Haemorrhage intracranial alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Headache alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 448 / 1771 (25.30%) 453 | | |
| Hypertonia alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Hypersomnia alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Hypotonia alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Infant irritability alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| IVth nerve paralysis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Lethargy alternative dictionary used: v26.1 26.1 | | | |

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|---|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Language disorder | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Migraine | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Motor developmental delay | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Movement disorder | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Myoclonus | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nerve compression | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Neurodevelopmental delay | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nystagmus | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

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|---|------------------|--|--|
| Paraesthesia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Presyncope | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Resting tremor | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sciatica | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | |
| occurrences (all) | 2 | | |
| Seizure | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Seizure like phenomena | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Subependymal cyst | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tethered cord syndrome | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Syncope | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|--|--|--|--|
| <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Tremor</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Tremor neonatal</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | | |
| <p>Blood and lymphatic system disorders</p> <p>Anaemia</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>9 / 1771 (0.51%)</p> <p>occurrences (all)</p> <p>9</p> <p>Anaemia neonatal</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Anaemia of pregnancy</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>1 / 1771 (0.06%)</p> <p>occurrences (all)</p> <p>1</p> <p>Bandaemia</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Haemorrhagic disease of newborn</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Hypochromic anaemia</p> <p>alternative dictionary used: v26.1 26.1</p> | | | |

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|---|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Iron deficiency anaemia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Leukopenia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lymph node pain | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lymphadenopathy | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Microcytic anaemia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Neutropenia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Polycythaemia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Splenomegaly | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|---|---|--|--|
| <p>Thrombocytopenia</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>1 / 1771 (0.06%)</p> <p>1</p> | | |
| <p>Thrombocytopenia neonatal</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 1771 (0.00%)</p> <p>0</p> | | |
| <p>Ear and labyrinth disorders</p> <p>Cerumen impaction</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Ear discomfort</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Ear pain</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Eustachian tube dysfunction</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Excessive cerumen production</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Middle ear effusion</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Middle ear inflammation</p> <p>alternative dictionary used: v26.1 26.1</p> | <p>0 / 1771 (0.00%)</p> <p>0</p> <p>0 / 1771 (0.00%)</p> <p>0</p> <p>0 / 1771 (0.00%)</p> <p>0</p> <p>0 / 1771 (0.00%)</p> <p>0</p> <p>0 / 1771 (0.00%)</p> <p>0</p> <p>0 / 1771 (0.00%)</p> <p>0</p> | | |

| | | | |
|--|--|--|--|
| <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Otorrhoea</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Tympanic membrane disorder</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Tympanic membrane hyperaemia</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Vertigo</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | | |
| <p>Eye disorders</p> <p>Amblyopia</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Blepharitis</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Chalazion</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Conjunctival haemorrhage</p> <p>alternative dictionary used: v26.1 26.1</p> | | | |

| | | | |
|---|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Conjunctival hyperaemia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Conjunctivitis allergic | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Corneal erosion | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dacryostenosis acquired | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dry eye | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eye discharge | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eye inflammation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eye swelling | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

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|--|------------------|--|--|
| Eyelid ptosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eyelid skin dryness | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Orbital oedema | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Periorbital oedema | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Strabismus | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Swelling of eyelid | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Trichiasis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vision blurred | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastrointestinal disorders | | | |

| | | | |
|--|-------------------------------|--|--|
| Abdominal distension alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Abdominal discomfort alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 1 / 1771 (0.06%) 1 | | |
| Abdominal hernia alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Abdominal pain upper alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 1 / 1771 (0.06%) 1 | | |
| Abdominal pain lower alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 4 / 1771 (0.23%) 4 | | |
| Abdominal pain alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 235 / 1771 (13.27%) 236 | | |
| Allergic colitis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Anal eczema alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Anal erythema alternative dictionary used: v26.1 26.1 | | | |

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|---|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Anal fissure | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Anal inflammation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Anal rash | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Aphthous ulcer | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Buccal polyp | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Colitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Constipation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 1771 (0.17%) | | |
| occurrences (all) | 3 | | |
| Constipation neonatal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

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|--|-------------------------------|--|--|
| Dental discomfort alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Diarrhoea haemorrhagic alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Diarrhoea alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 182 / 1771 (10.28%) 182 | | |
| Dyschezia alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Dyspepsia alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 3 / 1771 (0.17%) 3 | | |
| Dysphagia alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Enlarged uvula alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Enteritis alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Enterocolitis alternative dictionary used: v26.1 26.1 | | | |

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|--|-------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eosinophilic colitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Flatulence | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Food poisoning | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Frequent bowel movements | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastritis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastrointestinal disorder | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastroesophageal reflux disease | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 11 / 1771 (0.62%) | | |
| occurrences (all) | 11 | | |
| Gastroesophageal reflux in neonate | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

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|---|------------------|--|--|
| Gingival blister | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gingival cyst | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Haematochezia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Haematemesis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Haemorrhoids | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 1771 (0.17%) | | |
| occurrences (all) | 3 | | |
| Haemorrhoids thrombosed | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hyperchlorhydria | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Infantile colic | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Infant dyschezia | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|---------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Infantile spitting up | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Inguinal hernia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Meconium plug syndrome | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Mouth cyst | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Mouth ulceration | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | |
| occurrences (all) | 2 | | |
| Nausea | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 307 / 1771 (17.33%) | | |
| occurrences (all) | 310 | | |
| Oesophagitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Oral disorder | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

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|--|------------------|--|--|
| Peptic ulcer | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Proctitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Regurgitation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rectal prolapse | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Stomatitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Teething | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tooth demineralisation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tooth development disorder | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Toothache | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | |
|---|--|--|
| <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | |
| <p>Umbilical hernia</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | |
| <p>Upper gastrointestinal haemorrhage</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | |
| <p>Vomiting projectile</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | |
| <p>Vomiting</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>150 / 1771 (8.47%)</p> <p>occurrences (all)</p> <p>150</p> | | |
| <p>Skin and subcutaneous tissue disorders</p> <p>Acne infantile</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Alopecia</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Blister</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Cafe au lait spots</p> <p>alternative dictionary used: v26.1 26.1</p> | | |

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|--|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cellulite | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dermatitis allergic | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Decubitus ulcer | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dermatitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dermal cyst | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dermatitis atopic | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dermatitis contact | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Dermatitis diaper | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

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|--|------------------|--|--|
| Drug eruption | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dry skin | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eczema | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eczema asteatotic | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eczema infantile | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eczema nummular | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Erythema | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Erythema toxicum neonatorum | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hand dermatitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Herpes gestationis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hyperhidrosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ingrowing nail | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Intertrigo | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Macule | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Melanoderma | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Milia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Miliaria | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|---------------------------------------|------------------|--|--|
| Nail fold inflammation | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Papule | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Perioral dermatitis | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Petechiae | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pigmentation disorder | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pityriasis alba | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pityriasis rosea | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pityriasis | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Post inflammatory pigmentation change | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |

| | | | |
|--|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Prurigo | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pruritus | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 1771 (0.17%) | | |
| occurrences (all) | 3 | | |
| Rash macular | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rash maculo-papular | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rash morbilliform | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rash erythematous | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rash | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rash neonatal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|--|------------------|--|--|
| Rash papular | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rash pruritic | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Seborrhoea | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Seborrhoeic dermatitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin hyperpigmentation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin exfoliation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin hypopigmentation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin irritation | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin lesion | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|--|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin ulcer | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin mass | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Solar dermatitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Toxic skin eruption | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Transient neonatal pustular melanosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Urticaria | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Umbilical discharge | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Umbilical haemorrhage | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|--|---|--|--|
| <p>Urticaria papular</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 1771 (0.00%)</p> <p>0</p> | | |
| <p>Vitiligo</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 1771 (0.00%)</p> <p>0</p> | | |
| <p>Renal and urinary disorders</p> <p>Anuria</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Dysuria</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Haematuria</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Hydronephrosis</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Oliguria</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Pollakiuria</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Proteinuria</p> <p>alternative dictionary used: v26.1 26.1</p> | <p>0 / 1771 (0.00%)</p> <p>0</p> <p>0 / 1771 (0.00%)</p> <p>0</p> <p>0 / 1771 (0.00%)</p> <p>0</p> <p>0 / 1771 (0.00%)</p> <p>0</p> <p>0 / 1771 (0.00%)</p> <p>0</p> <p>1 / 1771 (0.06%)</p> <p>1</p> | | |

| | | |
|---|--|--|
| <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | |
| <p>Pyelocaliectasis</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | |
| <p>Renal colic</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>1 / 1771 (0.06%)</p> <p>occurrences (all)</p> <p>1</p> | | |
| <p>Urinary hesitation</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | |
| <p>Vesicoureteric reflux</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | |
| <p>Endocrine disorders</p> <p>Hypothyroidism</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Precocious puberty</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Thyroid dysfunction in pregnancy</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>0 / 1771 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Transient neonatal hyperthyrotropinaemia</p> <p>alternative dictionary used: v26.1 26.1</p> | | |

| | | | |
|---|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Acquired plagiocephaly | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Arthralgia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Asymmetric gluteal fold | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Asymmetric thigh fold | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Axillary mass | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Back pain | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 8 / 1771 (0.45%) | | |
| occurrences (all) | 8 | | |
| Bone disorder | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bone hypertrophy | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|--|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Foot deformity | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Head deformity | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypertonia neonatal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypotonia neonatal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Joint hyperextension | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Joint noise | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Joint laxity | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ligament laxity | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|---|-----------------------|--|--|
| Joint range of motion decreased alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Ligament pain alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 1 / 1771 (0.06%) 1 | | |
| Limb asymmetry alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Muscle spasms alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 2 / 1771 (0.11%) 2 | | |
| Muscle twitching alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Muscular weakness alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 1 / 1771 (0.06%) 1 | | |
| Musculoskeletal chest pain alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Myalgia alternative dictionary used: v26.1 26.1 subjects affected / exposed occurrences (all) | 0 / 1771 (0.00%) 0 | | |
| Musculoskeletal disorder alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|---|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Newborn head moulding | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nose deformity | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pain in extremity | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Posture abnormal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pubic pain | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Short stature | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Snapping hip syndrome | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Soft tissue mass | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|--|---|--|--|
| <p>Tendon disorder</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 1771 (0.00%)</p> <p>0</p> | | |
| <p>Torticollis</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 1771 (0.00%)</p> <p>0</p> | | |
| <p>Infections and infestations</p> <p>Abscess</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Abscess limb</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Acarodermatitis</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Acute sinusitis</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Adenoviral upper respiratory infection</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Adenovirus infection</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Amniotic cavity infection</p> <p>alternative dictionary used: v26.1</p> | <p>0 / 1771 (0.00%)</p> <p>0</p> <p>0 / 1771 (0.00%)</p> <p>0</p> <p>2 / 1771 (0.11%)</p> <p>2</p> <p>1 / 1771 (0.06%)</p> <p>1</p> <p>0 / 1771 (0.00%)</p> <p>0</p> <p>0 / 1771 (0.00%)</p> <p>0</p> | | |

| | | | |
|---|------------------|--|--|
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Amoebic dysentery | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Anal candidiasis | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Anal abscess | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ascariasis | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Asymptomatic bacteriuria | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | |
| occurrences (all) | 2 | | |
| Balanitis candida | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bartholin's abscess | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Beta haemolytic streptococcal infection | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |

| | | | |
|---|-------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bacterial disease carrier | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Bacterial vaginosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Body tinea | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Breast abscess | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bronchiolitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bronchitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| COVID-19 | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 23 / 1771 (1.30%) | | |
| occurrences (all) | 23 | | |
| Burkholderia mallei infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|---|------------------|--|--|
| Bullous impetigo | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Candida infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Candida nappy rash | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cellulitis orbital | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cellulitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Clostridium difficile infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Conjunctivitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Conjunctivitis viral | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Conjunctivitis bacterial | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|--|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Croup infectious | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cystitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dacryocystitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dengue fever | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dermatitis infected | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dermatophytosis of nail | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Diarrhoea infectious | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dysentery | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|-------------------------------------|------------------|--|--|
| Ear infection viral | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ear infection | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eczema impetiginous | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Enterovirus infection | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Enterobiasis | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eczema infected | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Erysipelas | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Erythema infectiosum | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Escherichia urinary tract infection | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |

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|--|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Exanthema subitum | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Escherichia infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Eye infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eye infection staphylococcal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eye infection viral | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eyelid infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Folliculitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Fungal infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

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|------------------------------------|------------------|--|--|
| Fungal skin infection | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Furuncle | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastrointestinal viral infection | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastroenteritis adenovirus | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastroenteritis bacterial | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastroenteritis norovirus | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastroenteritis viral | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastrointestinal infection | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastroenteritis | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |

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|---|------------------|--|--|
| subjects affected / exposed | 2 / 1771 (0.11%) | | |
| occurrences (all) | 2 | | |
| Genital candidiasis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Genital herpes | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Groin infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Groin abscess | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hand-foot-and-mouth disease | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Herpangina | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Herpes simplex | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Herpes virus infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

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|------------------------------------|------------------|--|--|
| Herpes zoster | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hordeolum | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Human herpesvirus 6 infection | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Impetigo | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Infected bite | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Influenza | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 2 / 1771 (0.11%) | | |
| occurrences (all) | 2 | | |
| Infection | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Laryngotracheitis obstructive | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Klebsiella urinary tract infection | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |

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|---|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Labyrinthitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Laryngitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Localised infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lower respiratory tract infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lower respiratory tract infection viral | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Mastitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Metapneumovirus bronchiolitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Metapneumovirus infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

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|--|------------------|--|--|
| Nail bed infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Myringitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Neonatal infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nasopharyngitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 9 / 1771 (0.51%) | | |
| occurrences (all) | 9 | | |
| Neonatal pneumonia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Norovirus infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Oral viral infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ophthalmia neonatorum | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Oral candidiasis | | | |
| alternative dictionary used: v26.1 26.1 | | | |

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|---|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Oral fungal infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Oral herpes | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Omphalitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Otitis externa | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Otitis externa fungal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Otitis media | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Otitis media acute | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Otitis media chronic | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

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|------------------------------------|------------------|--|--|--|
| Parasitic gastroenteritis | | | | |
| alternative dictionary used: v26.1 | | | | |
| 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Paronychia | | | | |
| alternative dictionary used: v26.1 | | | | |
| 26.1 | | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | | |
| occurrences (all) | 1 | | | |
| Parainfluenzae virus infection | | | | |
| alternative dictionary used: v26.1 | | | | |
| 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Periodontitis | | | | |
| alternative dictionary used: v26.1 | | | | |
| 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Pharyngitis | | | | |
| alternative dictionary used: v26.1 | | | | |
| 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Pharyngitis streptococcal | | | | |
| alternative dictionary used: v26.1 | | | | |
| 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Pharyngotonsillitis | | | | |
| alternative dictionary used: v26.1 | | | | |
| 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Pertussis | | | | |
| alternative dictionary used: v26.1 | | | | |
| 26.1 | | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Pneumonia | | | | |
| alternative dictionary used: v26.1 | | | | |
| 26.1 | | | | |

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|---|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pneumonia bacterial | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pneumonia mycoplasmal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pneumonia respiratory syncytial viral | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pneumonia viral | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Post procedural cellulitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pyoderma | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pustule | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Respiratory syncytial virus bronchiolitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

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| Respiratory syncytial virus bronchitis | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Respiratory syncytial virus infection | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Respiratory tract infection | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 5 / 1771 (0.28%) | | |
| occurrences (all) | 6 | | |
| Respiratory tract infection viral | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rhinitis | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rhinovirus infection | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Roseola | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Scarlet fever | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sepsis | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |

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| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sepsis neonatal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sinusitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Skin candida | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Subcutaneous abscess | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Subglottic laryngitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Suspected COVID-19 | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 1771 (0.17%) | | |
| occurrences (all) | 3 | | |
| Staphylococcal infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

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| Systemic viral infection | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Toxoplasmosis | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Thyroglossal cyst infection | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tinea capitis | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tinea infection | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tinea pedis | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tinea versicolour | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tonsillitis | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tracheitis | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |

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| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tracheobronchitis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Upper respiratory tract infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 15 / 1771 (0.85%) | | |
| occurrences (all) | 15 | | |
| Upper respiratory tract infection bacterial | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Urinary tract infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 21 / 1771 (1.19%) | | |
| occurrences (all) | 21 | | |
| Urogenital infection fungal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vaccination site abscess | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vaginal infection | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Varicella | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

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| Viral upper respiratory tract infection | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Viral diarrhoea | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Viral infection | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Viral pharyngitis | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Viral rash | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Viral rhinitis | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Viral tonsillitis | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Vulvovaginal candidiasis | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |
| subjects affected / exposed | 5 / 1771 (0.28%) | | |
| occurrences (all) | 5 | | |
| Vulvitis | | | |
| alternative dictionary used: v26.1 | | | |
| 26.1 | | | |

| | | | |
|--|--|--|--|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Vulvovaginal mycotic infection</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Wound infection</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>1 / 1771 (0.06%)</p> <p>1</p> <p>4 / 1771 (0.23%)</p> <p>4</p> <p>1 / 1771 (0.06%)</p> <p>1</p> | | |
| <p>Metabolism and nutrition disorders</p> <p>Abnormal loss of weight</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Breast milk substitute intolerance</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Cachexia</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Dairy intolerance</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Decreased appetite</p> <p>alternative dictionary used: v26.1 26.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Dehydration</p> <p>alternative dictionary used: v26.1 26.1</p> | <p>0 / 1771 (0.00%)</p> <p>0</p> <p>0 / 1771 (0.00%)</p> <p>0</p> <p>0 / 1771 (0.00%)</p> <p>0</p> <p>0 / 1771 (0.00%)</p> <p>0</p> <p>1 / 1771 (0.06%)</p> <p>1</p> | | |

| | | | |
|--|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Failure to thrive | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Fluid retention | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Food intolerance | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hyperglycaemia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypervitaminosis D | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypokalaemia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 1 / 1771 (0.06%) | | |
| occurrences (all) | 1 | | |
| Hypoglycaemia neonatal | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypoglycaemia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|---|------------------|--|--|
| Hypocalcaemia | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Iron deficiency | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 3 / 1771 (0.17%) | | |
| occurrences (all) | 3 | | |
| Lactose intolerance | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Malnutrition | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Metabolic acidosis | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Metabolic disorder | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Milk soy protein intolerance | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Obesity | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Overweight | | | |
| alternative dictionary used: v26.1 26.1 | | | |

| | | | |
|--|------------------|--|--|
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Poor feeding infant | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Underweight | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vitamin B12 deficiency | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vitamin D deficiency | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vitamin K deficiency | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |
| Weight gain poor | | | |
| alternative dictionary used: v26.1 26.1 | | | |
| subjects affected / exposed | 0 / 1771 (0.00%) | | |
| occurrences (all) | 0 | | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|------------------|--|
| 05 October 2020 | The following points have been amended: Case definitions for lower respiratory tract illness have been modified to include the phrase "medically assessed." In addition, the success criteria for the primary objective on any RSV-associated lower respiratory tract infection has been changed. Previously the lower bound of this primary endpoint was 10%; it has been increased to 20%. The timing of interim analyses have been modified to make overall interim analyses operationally pragmatic. In addition, the corresponding study design operational characteristics have been updated. |
| 23 June 2021 | This protocol has been amended to: <ul style="list-style-type: none">• implement the changes discussed and agreed with Center for Biologics Evaluation and Research (CBER).• extend the infant respiratory tract illness (RTI) surveillance to 12 months to ensure that this period will cover at least 1 full RSV season.• remove the collection of hematocrit samples due to challenges (mostly due to the COVID-19 pandemic) faced in several countries preventing the samples from reaching the central lab in adequate time for testing.• define an additional population for analysis: Modified Full Analysis - Efficacy Set. |
| 10 February 2022 | This protocol has been amended to: <ul style="list-style-type: none">• change the trigger point for interim analyses which could lead to claim vaccine efficacy (2, 3 and 4) as there is a high chance of claiming vaccine efficacy (VE) earlier than initially anticipated.• add 2 new secondary descriptive efficacy objectives to assess VE against severe medically assessed LRTIs and any medically assessed LRTIs associated to RSV subtypes A and B separately in the infant participants from birth up to 6 months of age.• acquire further information on how the VE can be sustained up to 12 months post-birth.• remove the distribution of antibody titers/concentrations and the scatter plots showing the individual post-vaccination versus pre-vaccination results as well as scatter plots showing relationship between maternal and infants antibody titers. These analyses have already been described as part of previous completed RSV MAT studies and performing them in RSV MAT-009 (i.e. a larger sample size), is not expected to provide any additional critical information with regards to the study vaccine immunogenicity.• remove the section about predicted VE based on surrogate endpoint due to the limitation of data from internal epidemiological studies. Hence, the surrogate endpoint model cannot be robustly established and validated. |
| 15 March 2022 | Following a recommendation from the Independent Data Monitoring Committee of NCT04605159 (RSV MAT 009), GSK made the decision to stop enrolment and vaccination in the study. Ongoing study participants at that time continued to be monitored as part of the study. The Protocol was updated to reflect the change to study's safety assessment plan. |

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| 23 February 2023 | <p>The following points have been amended:</p> <ul style="list-style-type: none">• The Benefit/Risk assessment has been updated to clarify the status of the safety signals after GSK's signal validation process.• The objectives and outcome measures section was updated.• RSV IgG antibody concentrations would be assessed only in maternal blood samples collected at delivery and cord blood* [*or an infant blood sample collected within 72 hours after birth (if no cord blood sample can be obtained)].• RSV-B neutralizing antibody titers were removed from the secondary immunogenicity analysis.• Populations for analysis were updated to reflect the changes to the statistical analysis plan of the study, following the of decision to stop further enrolment and vaccination.• Country-specific requirements have been added for Spain and Argentina. |
|------------------|---|

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported