



Clinical trial results:

A Phase 3, Randomized, Active-Controlled, Double-blind Trial Evaluating the Impact of a 13-valent Pneumococcal Conjugate Vaccine on Nasopharyngeal Colonization With Vaccine Serotypes of Streptococcus Pneumoniae in Healthy Infants in Israel.

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2008-003708-77 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 08 August 2011 |

Results information

| | |
|--------------------------------|----------------|
| Result version number | v1 (current) |
| This version publication date | 29 June 2016 |
| First version publication date | 01 August 2015 |

Trial information

Trial identification

| | |
|-----------------------|-------------|
| Sponsor protocol code | 6096A1-3006 |
|-----------------------|-------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT00508742 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Pfizer Inc. |
| Sponsor organisation address | 235 E 42nd Street, New York, United States, NY 10017 |
| Public contact | Clinical Trials.gov Call Center, Pfizer Inc, 001 8007181021, ClinicalTrials.govCallCenter@pfizer.com |
| Scientific contact | Clinical Trials.gov Call Center, Pfizer Inc, 001 800-718-1021, ClinicalTrials.govCallCenter@pfizer.com |

Notes:

Paediatric regulatory details

| | |
|--|---------------------|
| Is trial part of an agreed paediatric investigation plan (PIP) | Yes |
| EMA paediatric investigation plan number(s) | EMA-000036-PIP01-07 |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | Yes |

Notes:

Results analysis stage

| | |
|--|------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 28 February 2012 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 08 August 2011 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that 13-Valent Pneumococcal Conjugate Vaccine (13vPnC) reduces newly identified nasopharyngeal acquisitions of Streptococcus pneumoniae (S pneumoniae) serotypes 6A and 19A combined compared with 7-valent pneumococcal conjugate vaccine (7vPnC) from 1 month after the infant series to 24 months of age.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 11 February 2008 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|--------------|
| Country: Number of subjects enrolled | Israel: 1866 |
| Worldwide total number of subjects | 1866 |
| EEA total number of subjects | 0 |

Notes:

Subjects enrolled per age group

| | |
|---|------|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 1866 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

This study was conducted at 11 sites in Israel between 11 Feb 2008 to 8 Aug 2011. Total 1866 subjects were enrolled and received 13vPnC or 7vPnC at 2, 4, and 6 months of age (infant series) and 12 months of age (toddler dose).

Period 1

| | |
|------------------------------|--|
| Period 1 title | Infant Series |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Carer, Assessor |

Arms

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

| | |
|------------------|----------------------|
| Arm title | 13vPnC Infant series |
|------------------|----------------------|

Arm description:

13vPnC administered at 2, 4, and 6 months of age.

| | |
|--|-------------------|
| Arm type | Experimental |
| Investigational medicinal product name | 13vPnC |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Subjects received 0.5 milliliter (mL) dose of 13vPnC at 2, 4, and 6 months of age.

| | |
|------------------|---------------------|
| Arm title | 7vPnC Infant series |
|------------------|---------------------|

Arm description:

7vPnC administered at 2, 4, and 6 months of age.

| | |
|--|-------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | 7vPnC |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Subjects received 0.5 mL dose of 7vPnC at 2, 4, and 6 months of age.

| Number of subjects in period 1 | 13vPnC Infant series | 7vPnC Infant series |
|--|----------------------|---------------------|
| Started | 932 | 934 |
| Vaccinated Dose 1 (at 2 Months of Age) | 930 | 933 |
| Vaccinated Dose 2 (at 4 Months of Age) | 904 | 902 |
| Vaccinated Dose 3 (at 6 Months of Age) | 898 | 892 |
| Completed | 890 | 889 |
| Not completed | 42 | 45 |
| Physician decision | 1 | - |
| Adverse Event | 5 | 4 |
| Protocol Violation | 1 | - |
| Unspecified | 4 | 1 |
| Parent/Legal Guardian Request | 31 | 40 |

Period 2

| | |
|------------------------------|--|
| Period 2 title | After Infant Series |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Carer, Assessor |

Arms

| | |
|------------------------------|----------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | 13vPnC After Infant series |

Arm description:

Subjects who received 13vPnC at 2, 4, and 6 months of age.

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

| | |
|------------------|---------------------------|
| Arm title | 7vPnC After Infant series |
|------------------|---------------------------|

Arm description:

Subjects who received 7vPnC at 2, 4, and 6 months of age.

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

| Number of subjects in period 2 | 13vPnC After Infant series | 7vPnC After Infant series |
|---------------------------------------|----------------------------|---------------------------|
| Started | 890 | 889 |
| Completed | 883 | 878 |
| Not completed | 7 | 11 |
| Adverse Event | 2 | 6 |

| | | |
|-------------------------------|---|---|
| Unspecified | 2 | 1 |
| Protocol Violation | 1 | - |
| Failed to Return | 1 | - |
| Lost to follow-up | 1 | 1 |
| Parent/Legal Guardian Request | - | 3 |

Period 3

| | |
|------------------------------|--|
| Period 3 title | Toddler Dose |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Carer, Assessor |

Arms

| | |
|------------------------------|---------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | 13vPnC Toddler dose |

Arm description:

13vPnC administered at 12 months of age.

| | |
|--|-------------------|
| Arm type | Experimental |
| Investigational medicinal product name | 13vPnC |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Subjects received 0.5 mL dose of 13vPnC at 12 months of age.

| | |
|------------------|--------------------|
| Arm title | 7vPnC Toddler dose |
|------------------|--------------------|

Arm description:

7vPnC administered at 12 months of age.

| | |
|--|-------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | 7vPnC |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Subjects received 0.5 mL dose of 7vPnC at 12 months of age.

| Number of subjects in period 3 | 13vPnC Toddler dose | 7vPnC Toddler dose |
|---------------------------------------|---------------------|--------------------|
| Started | 883 | 878 |
| Completed | 858 | 863 |
| Not completed | 25 | 15 |
| Adverse Event | 1 | - |
| Unspecified | 5 | 4 |
| Lost to follow-up | 2 | 3 |
| Parent/Legal Guardian Request | 17 | 8 |

Baseline characteristics

Reporting groups

| | |
|---|----------------------|
| Reporting group title | 13vPnC Infant series |
| Reporting group description: 13vPnC administered at 2, 4, and 6 months of age. | |
| Reporting group title | 7vPnC Infant series |
| Reporting group description: 7vPnC administered at 2, 4, and 6 months of age. | |

| Reporting group values | 13vPnC Infant series | 7vPnC Infant series | Total |
|--|----------------------|---------------------|-------|
| Number of subjects | 932 | 934 | 1866 |
| Age categorical Units: Subjects | | | |
| Age continuous Units: months arithmetic mean standard deviation | 2.2 ± 0.3 | 2.2 ± 0.3 | - |
| Gender categorical Units: Subjects | | | |
| Female | 474 | 471 | 945 |
| Male | 458 | 463 | 921 |

Subject analysis sets

| | |
|--|--------------|
| Subject analysis set title | 13vPnC |
| Subject analysis set type | Per protocol |
| Subject analysis set description: 13vPnC 0.5 mL dose administered intramuscularly at 2, 4, and 6 months of age (infant series) and 12 months of age (toddler dose). | |
| Subject analysis set title | 7vPnC |
| Subject analysis set type | Per protocol |
| Subject analysis set description: 7vPnC 0.5 mL dose administered intramuscularly at 2, 4, and 6 months of age (infant series) and 12 months of age (toddler dose). | |

| Reporting group values | 13vPnC | 7vPnC | |
|--|--------------|--------------|--|
| Number of subjects | 881 | 873 | |
| Age categorical Units: Subjects | | | |
| Age continuous Units: months arithmetic mean standard deviation | 2.2 ± 0.3 | 2.2 ± 0.3 | |
| Gender categorical Units: Subjects | | | |
| Female | | | |

| | | | |
|------|--|--|--|
| Male | | | |
|------|--|--|--|

End points

End points reporting groups

| | |
|-----------------------------------|---|
| Reporting group title | 13vPnC Infant series |
| Reporting group description: | 13vPnC administered at 2, 4, and 6 months of age. |
| Reporting group title | 7vPnC Infant series |
| Reporting group description: | 7vPnC administered at 2, 4, and 6 months of age. |
| Reporting group title | 13vPnC After Infant series |
| Reporting group description: | Subjects who received 13vPnC at 2, 4, and 6 months of age. |
| Reporting group title | 7vPnC After Infant series |
| Reporting group description: | Subjects who received 7vPnC at 2, 4, and 6 months of age. |
| Reporting group title | 13vPnC Toddler dose |
| Reporting group description: | 13vPnC administered at 12 months of age. |
| Reporting group title | 7vPnC Toddler dose |
| Reporting group description: | 7vPnC administered at 12 months of age. |
| Subject analysis set title | 13vPnC |
| Subject analysis set type | Per protocol |
| Subject analysis set description: | 13vPnC 0.5 mL dose administered intramuscularly at 2, 4, and 6 months of age (infant series) and 12 months of age (toddler dose). |
| Subject analysis set title | 7vPnC |
| Subject analysis set type | Per protocol |
| Subject analysis set description: | 7vPnC 0.5 mL dose administered intramuscularly at 2, 4, and 6 months of age (infant series) and 12 months of age (toddler dose). |

Primary: Percentage of Subjects With a New Acquisition of Serotype 6A' (6A + 6C) or 19A Combined 1 Month After the Infant Series to 24 Months of Age

| | |
|------------------------|---|
| End point title | Percentage of Subjects With a New Acquisition of Serotype 6A' (6A + 6C) or 19A Combined 1 Month After the Infant Series to 24 Months of Age |
| End point description: | A new acquisition was defined as the detection of a serotype (here 6A' [6A + 6C] or 19A), once a subject was fully vaccinated (one month after dose 3), that had not been detected previously in the baseline samples at 2, 4, 6 months of age. Evaluable culture population included all subjects who adhered to protocol requirements; received the treatment to which they were randomized; had at least 1 nasopharyngeal swab for the proposed analysis and no major protocol violations. |
| End point type | Primary |
| End point timeframe: | Month 7 through Month 24 |

| End point values | 13vPnC | 7vPnC | | |
|----------------------------------|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 881 | 873 | | |
| Units: percentage of subjects | | | | |
| number (confidence interval 95%) | 20 (17.4 to 22.8) | 36 (32.8 to 39.3) | | |

Statistical analyses

| Statistical analysis title | Serotype 6A' (6A + 6C) or 19A |
|---|-------------------------------|
| Comparison groups | 7vPnC v 13vPnC |
| Number of subjects included in analysis | 1754 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Rate Ratio |
| Point estimate | 0.56 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.47 |
| upper limit | 0.65 |

Secondary: Percentage of Subjects With Nasopharyngeal Cultures Testing Positive for 6A' (6A + 6C) or 19A Serotypes of Streptococcus pneumoniae (S. pneumoniae) at 7, 12, 13, 18 and 24 Months of Age

| | |
|-----------------|---|
| End point title | Percentage of Subjects With Nasopharyngeal Cultures Testing Positive for 6A' (6A + 6C) or 19A Serotypes of Streptococcus pneumoniae (S. pneumoniae) at 7, 12, 13, 18 and 24 Months of Age |
|-----------------|---|

End point description:

Percentage of Subjects With Nasopharyngeal Cultures Testing Positive for 6A' (6A + 6C) or 19A Serotypes of S. pneumoniae at 7, 12, 13, 18 and 24 Months of Age. Evaluable culture population; 'n' is number of subjects with at least 1 determinate nasopharyngeal culture result for given serotype combination at specified time points for each arm group respectively.

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

End point timeframe:

Month 7, 12, 13, 18, 24

| End point values | 13vPnC | 7vPnC | | |
|----------------------------------|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 881 | 873 | | |
| Units: percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| Month 7 (n= 881, 871) | 7.3 (5.6 to 9.2) | 10.9 (8.9 to 13.2) | | |

| | | | | |
|------------------------|-------------------|---------------------|--|--|
| Month 12 (n= 881, 873) | 8.1 (6.3 to 10.1) | 13.7 (11.5 to 16.2) | | |
| Month 13 (n= 871, 870) | 5.4 (4 to 7.1) | 13.6 (11.4 to 16) | | |
| Month 18 (n= 864, 864) | 7.1 (5.4 to 9) | 13.5 (11.3 to 16) | | |
| Month 24 (n= 855, 856) | 6.2 (4.7 to 8) | 10.7 (8.8 to 13) | | |

Statistical analyses

| | |
|--|-----------------|
| Statistical analysis title | Month 7 |
| Statistical analysis description: 13vPnC/7vPnC, odds ratio was calculated using a logistic regression model with treatment group as the independent variable. | |
| Comparison groups | 7vPnC v 13vPnC |
| Number of subjects included in analysis | 1754 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 0.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.5 |
| upper limit | 0.9 |

| | |
|--|-----------------|
| Statistical analysis title | Month 12 |
| Statistical analysis description: 13vPnC/7vPnC, odds ratio was calculated using a logistic regression model with treatment group as the independent variable. | |
| Comparison groups | 13vPnC v 7vPnC |
| Number of subjects included in analysis | 1754 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 0.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.4 |
| upper limit | 0.7 |

| | |
|--|----------|
| Statistical analysis title | Month 13 |
| Statistical analysis description: 13vPnC/7vPnC, odds ratio was calculated using a logistic regression model with treatment group as the | |

independent variable.

| | |
|---|-----------------|
| Comparison groups | 13vPnC v 7vPnC |
| Number of subjects included in analysis | 1754 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 0.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.3 |
| upper limit | 0.5 |

| | |
|-----------------------------------|----------|
| Statistical analysis title | Month 18 |
|-----------------------------------|----------|

Statistical analysis description:

13vPnC/7vPnC, odds ratio was calculated using a logistic regression model with treatment group as the independent variable.

| | |
|---|-----------------|
| Comparison groups | 13vPnC v 7vPnC |
| Number of subjects included in analysis | 1754 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 0.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.4 |
| upper limit | 0.7 |

| | |
|-----------------------------------|----------|
| Statistical analysis title | Month 24 |
|-----------------------------------|----------|

Statistical analysis description:

13vPnC/7vPnC, odds ratio was calculated using a logistic regression model with treatment group as the independent variable.

| | |
|---|-----------------|
| Comparison groups | 13vPnC v 7vPnC |
| Number of subjects included in analysis | 1754 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 0.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.4 |
| upper limit | 0.8 |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse Events (AEs)/Serious Adverse Events (SAEs): recorded from signing of informed consent form to completion of study.

Adverse event reporting additional description:

Safety population: all randomized subjects with at least 1 dose of study treatment. Same event may appear as both an AE and a SAE. However, what is presented are distinct events. An event may be categorized as serious in 1 subject and as non serious in another, or one subject may have experienced both a serious and non serious event during study.

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 14.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|----------------------|
| Reporting group title | Infant Series 13vPnC |
|-----------------------|----------------------|

Reporting group description:

Subjects who received 13vPnC 0.5 mL intramuscularly at 2, 4 and 6 months of age (infant series), assessed from dose 1 of the infant series through the blood draw 1 month after the infant series.

| | |
|-----------------------|---------------------|
| Reporting group title | Infant Series 7vPnC |
|-----------------------|---------------------|

Reporting group description:

Subjects who received 7vPnC 0.5 mL intramuscularly at 2, 4 and 6 months of age (infant series), assessed from dose 1 of the infant series through the blood draw 1 month after the infant series.

| | |
|-----------------------|----------------------------|
| Reporting group title | After Infant Series 13vPnC |
|-----------------------|----------------------------|

Reporting group description:

Subjects who received 13vPnC 0.5 mL intramuscularly at 2, 4, and 6 months of age in infant series, assessed after the infant series blood draw to the toddler dose.

| | |
|-----------------------|---------------------------|
| Reporting group title | After Infant Series 7vPnC |
|-----------------------|---------------------------|

Reporting group description:

Subjects who received 7vPnC 0.5 mL intramuscularly at 2, 4, and 6 months of age in infant series, assessed after the infant series blood draw to the toddler dose.

| | |
|-----------------------|---------------------|
| Reporting group title | Toddler Dose 13vPnC |
|-----------------------|---------------------|

Reporting group description:

Subjects who received 13vPnC 0.5 mL intramuscularly at 12 months of age (toddler dose), assessed from the toddler dose through the blood draw 1 month after the toddler dose.

| | |
|-----------------------|--------------------|
| Reporting group title | Toddler Dose 7vPnC |
|-----------------------|--------------------|

Reporting group description:

Subjects who received 7vPnC 0.5 mL dose intramuscularly at 12 months of age (toddler dose), assessed from the toddler dose through the blood draw 1 month after the toddler dose.

| | |
|-----------------------|---------------------------|
| Reporting group title | After Toddler Dose 13vPnC |
|-----------------------|---------------------------|

Reporting group description:

Subjects who received 13vPnC 0.5 mL intramuscularly at 12 months of age in toddler dose, assessed after the toddler dose blood draw through the Month 24 visit.

| | |
|-----------------------|--------------------------|
| Reporting group title | After Toddler Dose 7vPnC |
|-----------------------|--------------------------|

Reporting group description:

Subjects who received 7vPnC 0.5 mL intramuscularly at 12 months of age in toddler dose, assessed after the toddler dose blood draw through the Month 24 visit.

| Serious adverse events | Infant Series 13vPnC | Infant Series 7vPnC | After Infant Series 13vPnC |
|---|-------------------------|---------------------|-------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 64 / 930 (6.88%) | 57 / 933 (6.11%) | 48 / 929 (5.17%) |
| number of deaths (all causes) | 1 | 0 | 0 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Medulloblastoma | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 0 / 929 (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 | | | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Cephalhaematoma | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 0 / 929 (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 | | | |
| Irritability | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 0 / 929 (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 | | | |
| subjects affected / exposed | 8 / 930 (0.86%) | 4 / 933 (0.43%) | 6 / 929 (0.65%) |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 4 | 0 / 6 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sudden death | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Gait disturbance | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Immune system disorders | | | |
| Milk allergy | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Social circumstances | | | |
| Overfeeding of infant | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 2 / 933 (0.21%) | 0 / 929 (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 | | | |
| Testicular torsion | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Apparent life threatening event | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Asthma | | | |
| subjects affected / exposed | 2 / 930 (0.22%) | 0 / 933 (0.00%) | 3 / 929 (0.32%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 0 / 929 (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 |
| Choking | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 3 / 930 (0.32%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Cough | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 2 / 933 (0.21%) | 0 / 929 (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 |
| Grunting | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 0 / 929 (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 |
| Lung infiltration | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Respiratory distress | | | |
| subjects affected / exposed | 2 / 930 (0.22%) | 1 / 933 (0.11%) | 1 / 929 (0.11%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sleep apnoea syndrome | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 0 / 929 (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 |
| Stridor | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 0 / 933 (0.00%) | 1 / 929 (0.11%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Wheezing | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 2 / 930 (0.22%) | 0 / 933 (0.00%) | 2 / 929 (0.22%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haemoptysis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Breath holding | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 1 / 933 (0.11%) | 1 / 929 (0.11%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Restlessness | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 1 / 933 (0.11%) | 0 / 929 (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 |
| Apathy | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Investigations | | | |
| Urine analysis abnormal | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Influenza virus test positive | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| complications | | | |
| Fall | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 0 / 929 (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 |
| Head injury | | | |
| subjects affected / exposed | 3 / 930 (0.32%) | 2 / 933 (0.21%) | 1 / 929 (0.11%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Post procedural haemorrhage | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 0 / 929 (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 |
| Skull fracture | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 1 / 929 (0.11%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Burns second degree | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Exposure to toxic agent | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Foreign body | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 1 / 929 (0.11%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Near drowning | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Thermal burn | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 fractured base | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Laceration | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Accidental poisoning | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Contusion | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Femur fracture | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Hand fracture | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Mouth injury | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Postoperative fever | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Radius fracture | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Road traffic accident | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Congenital, familial and genetic disorders | | | |
| Ventricular septal defect | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Cardiac failure congestive | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Cyanosis | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 2 / 933 (0.21%) | 0 / 929 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Cerebral infarction | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 0 / 929 (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 |
| Convulsion | | | |
| subjects affected / exposed | 2 / 930 (0.22%) | 2 / 933 (0.21%) | 1 / 929 (0.11%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Febrile convulsion | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 2 / 933 (0.21%) | 3 / 929 (0.32%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fontanelle bulging | | | |
| subjects affected / exposed | 2 / 930 (0.22%) | 3 / 933 (0.32%) | 0 / 929 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypotonia | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 0 / 929 (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 |
| Partial seizures | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 0 / 929 (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 |
| Status epilepticus | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 spasms | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 1 / 929 (0.11%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myoclonic epilepsy | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Leukocytosis | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 0 / 933 (0.00%) | 1 / 929 (0.11%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lymphadenitis | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 1 / 929 (0.11%) |
| 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 | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Eye movement disorder | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 0 / 929 (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 |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Corneal perforation | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 3 / 930 (0.32%) | 1 / 933 (0.11%) | 2 / 929 (0.22%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intussusception | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 1 / 933 (0.11%) | 0 / 929 (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 |
| Oral disorder | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 0 / 929 (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 |
| Vomiting | | | |
| subjects affected / exposed | 2 / 930 (0.22%) | 5 / 933 (0.54%) | 2 / 929 (0.22%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Aphthous stomatitis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Haematemesis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 0 / 929 (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 |
| Stomatitis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 1 / 929 (0.11%) |
| 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 | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 | | | |
| Hepatomegaly | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Skin and subcutaneous tissue disorders | | | |
| Rash | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 0 / 929 (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 |
| Rash maculo-papular | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 930 (0.11%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Henoch-Schonlein purpura | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 1 / 929 (0.11%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Petechiae | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Renal and urinary disorders | | | |
| Leukocyturia | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Kidney enlargement | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Dysuria | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 | | | |

| | | | |
|---|------------------|-----------------|-----------------|
| Trigger finger | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Monarthrititis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Anal abscess | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 0 / 929 (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 |
| Bacteraemia | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 0 / 929 (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 |
| Bronchiolitis | | | |
| subjects affected / exposed | 10 / 930 (1.08%) | 8 / 933 (0.86%) | 3 / 929 (0.32%) |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 8 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Bronchitis viral | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Croup infectious | | | |

| | | | |
|---|------------------|-----------------|------------------|
| subjects affected / exposed | 1 / 930 (0.11%) | 0 / 933 (0.00%) | 0 / 929 (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 | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 0 / 933 (0.00%) | 1 / 929 (0.11%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 11 / 930 (1.18%) | 8 / 933 (0.86%) | 12 / 929 (1.29%) |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 8 | 0 / 12 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 4 / 933 (0.43%) | 5 / 929 (0.54%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | 0 / 5 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Meningitis aseptic | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 1 / 933 (0.11%) | 0 / 929 (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 |
| Meningitis viral | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Meningococcal infection | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 0 / 929 (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 | | | |
| subjects affected / exposed | 3 / 930 (0.32%) | 5 / 933 (0.54%) | 9 / 929 (0.97%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | 0 / 9 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media acute | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 2 / 930 (0.22%) | 2 / 933 (0.21%) | 0 / 929 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pertussis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 0 / 929 (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 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 0 / 929 (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 | | | |
| subjects affected / exposed | 2 / 930 (0.22%) | 1 / 933 (0.11%) | 5 / 929 (0.54%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | 0 / 5 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Postoperative wound infection | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Respiratory syncytial virus bronchiolitis | | | |
| subjects affected / exposed | 3 / 930 (0.32%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 1 / 929 (0.11%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rotavirus infection | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Streptococcal bacteraemia | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 930 (0.11%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 4 / 930 (0.43%) | 4 / 933 (0.43%) | 1 / 929 (0.11%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 3 / 933 (0.32%) | 1 / 929 (0.11%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral infection | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Escherichia urinary tract infection | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Exanthema subitum | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 1 / 929 (0.11%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Osteomyelitis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 1 / 929 (0.11%) |
| 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 rotavirus | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 1 / 929 (0.11%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Parainfluenzae virus infection | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Periorbital cellulitis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Pneumococcal bacteraemia | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia influenzal | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia viral | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Herpangina | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Arthritis bacterial | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Cellulitis | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Corynebacterium infection | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Endophthalmitis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| H1N1 influenza | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Influenza | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Intervertebral discitis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Localised infection | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia respiratory syncytial viral | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Pulmonary tuberculosis | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Tooth abscess | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Wound infection | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Acute tonsillitis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 1 / 933 (0.11%) | 1 / 929 (0.11%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diet refusal | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Lactose intolerance | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 2 / 930 (0.22%) | 0 / 933 (0.00%) | 0 / 929 (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 |
| Metabolic acidosis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 0 / 929 (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 |
| Weight gain poor | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 0 / 929 (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 |
| Feeding disorder | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 1 / 929 (0.11%) |
| 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 | After Infant Series 7vPnC | Toddler Dose 13vPnC | Toddler Dose 7vPnC |
|--|------------------------------|------------------------|--------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 64 / 931 (6.87%) | 15 / 882 (1.70%) | 23 / 875 (2.63%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Medulloblastoma | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 1 / 875 (0.11%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Cephalhaematoma | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Irritability | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Pyrexia | | | |
| subjects affected / exposed | 4 / 931 (0.43%) | 0 / 882 (0.00%) | 4 / 875 (0.46%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sudden death | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Gait disturbance | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 1 / 875 (0.11%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Milk allergy | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Social circumstances | | | |
| Overfeeding of infant | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| Testicular torsion | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Apparent life threatening event | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Asthma | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 1 / 882 (0.11%) | 2 / 875 (0.23%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Choking | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Cough | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 2 / 882 (0.23%) | 0 / 875 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Grunting | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Lung infiltration | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory distress | | | |
| subjects affected / exposed | 2 / 931 (0.21%) | 1 / 882 (0.11%) | 2 / 875 (0.23%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sleep apnoea syndrome | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 1 / 875 (0.11%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Stridor | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 1 / 882 (0.11%) | 0 / 875 (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 |
| Wheezing | | | |
| subjects affected / exposed | 2 / 931 (0.21%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Haemoptysis | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Breath holding | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Restlessness | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Apathy | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Investigations | | | |
| Urine analysis abnormal | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Influenza virus test positive | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Fall | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Head injury | | | |
| subjects affected / exposed | 4 / 931 (0.43%) | 0 / 882 (0.00%) | 2 / 875 (0.23%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Post procedural haemorrhage | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (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 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Burns second degree | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Exposure to toxic agent | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Foreign body | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Near drowning | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Thermal burn | | | |
| subjects affected / exposed | 2 / 931 (0.21%) | 1 / 882 (0.11%) | 1 / 875 (0.11%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skull fractured base | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Laceration | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 1 / 882 (0.11%) | 0 / 875 (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 |
| Accidental poisoning | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Contusion | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Femur fracture | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Hand fracture | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Mouth injury | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Postoperative fever | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Radius fracture | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Road traffic accident | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Congenital, familial and genetic disorders | | | |
| Ventricular septal defect | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| Cardiac failure congestive | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Cyanosis | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 1 / 882 (0.11%) | 0 / 875 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Cerebral infarction | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Convulsion | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Febrile convulsion | | | |
| subjects affected / exposed | 5 / 931 (0.54%) | 1 / 882 (0.11%) | 1 / 875 (0.11%) |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fontanelle bulging | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Hypotonia | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Partial seizures | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Status epilepticus | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Infantile spasms | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Myoclonic epilepsy | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Leukocytosis | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Lymphadenitis | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Anaemia | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Eye movement disorder | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Conjunctivitis | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Corneal perforation | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 2 / 931 (0.21%) | 0 / 882 (0.00%) | 1 / 875 (0.11%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intussusception | | | |
| subjects affected / exposed | 3 / 931 (0.32%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Oral disorder | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 4 / 875 (0.46%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Aphthous stomatitis | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Haematemesis | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Stomatitis | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 | | | |
| Hepatomegaly | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 1 / 875 (0.11%) |
| 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 and subcutaneous tissue disorders | | | |
| Rash | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Henoch-Schonlein purpura | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Rash macular | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Petechiae | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Pruritus | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Renal and urinary disorders | | | |
| Leukocyturia | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Kidney enlargement | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 1 / 875 (0.11%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dysuria | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 | | | |
| Trigger finger | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 1 / 882 (0.11%) | 0 / 875 (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 |
| Monarthritis | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Anal abscess | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 1 / 875 (0.11%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|------------------|-----------------|-----------------|
| Bacteraemia | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Bronchiolitis | | | |
| subjects affected / exposed | 4 / 931 (0.43%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 1 / 875 (0.11%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis viral | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Croup infectious | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Dysentery | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 1 / 882 (0.11%) | 0 / 875 (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 | | | |
| subjects affected / exposed | 13 / 931 (1.40%) | 3 / 882 (0.34%) | 4 / 875 (0.46%) |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 3 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 4 / 931 (0.43%) | 0 / 882 (0.00%) | 1 / 875 (0.11%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Meningitis aseptic | | | |

| | | | |
|---|------------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Meningitis viral | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Meningococcal infection | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Otitis media | | | |
| subjects affected / exposed | 10 / 931 (1.07%) | 1 / 882 (0.11%) | 3 / 875 (0.34%) |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 1 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Pertussis | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Pharyngitis | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Pneumonia | | | |
| subjects affected / exposed | 7 / 931 (0.75%) | 0 / 882 (0.00%) | 1 / 875 (0.11%) |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Postoperative wound infection | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus bronchiolitis | | | |
| subjects affected / exposed | 3 / 931 (0.32%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 1 / 875 (0.11%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rotavirus infection | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Streptococcal bacteraemia | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 2 / 931 (0.21%) | 0 / 882 (0.00%) | 2 / 875 (0.23%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 1 / 875 (0.11%) |
| 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 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Exanthema subitum | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Osteomyelitis | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (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 rotavirus | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Parainfluenzae virus infection | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Periorbital cellulitis | | | |
| subjects affected / exposed | 2 / 931 (0.21%) | 1 / 882 (0.11%) | 0 / 875 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumococcal bacteraemia | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Pneumonia influenzal | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Pneumonia viral | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Herpangina | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 1 / 882 (0.11%) | 0 / 875 (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 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 1 / 882 (0.11%) | 0 / 875 (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 |
| Arthritis bacterial | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Corynebacterium infection | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Endophthalmitis | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| H1N1 influenza | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Influenza | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Intervertebral discitis | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Localised infection | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia respiratory syncytial viral | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Pulmonary tuberculosis | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Tooth abscess | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Wound infection | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Acute tonsillitis | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 1 / 882 (0.11%) | 0 / 875 (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 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 2 / 875 (0.23%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diet refusal | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Lactose intolerance | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Metabolic acidosis | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Weight gain poor | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (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 |
| Feeding disorder | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|-------------------------------|--------------------|--------------------|--|
| Serious adverse events | After Toddler Dose | After Toddler Dose | |
|-------------------------------|--------------------|--------------------|--|

| | 13vPnC | 7vPnC | |
|---|-------------------|------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 91 / 882 (10.32%) | 73 / 875 (8.34%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Medulloblastoma | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pregnancy, puerperium and perinatal conditions | | | |
| Cephalhaematoma | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General disorders and administration site conditions | | | |
| Irritability | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyrexia | | | |
| subjects affected / exposed | 11 / 882 (1.25%) | 10 / 875 (1.14%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sudden death | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gait disturbance | | | |

| | | | |
|--|-----------------|-----------------|--|
| subjects affected / exposed | 3 / 882 (0.34%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Immune system disorders | | | |
| Milk allergy | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Social circumstances | | | |
| Overfeeding of infant | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Reproductive system and breast disorders | | | |
| Testicular torsion | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Apparent life threatening event | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Asthma | | | |
| subjects affected / exposed | 7 / 882 (0.79%) | 5 / 875 (0.57%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Choking | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cough | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 2 / 875 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Grunting | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung infiltration | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 3 / 875 (0.34%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory distress | | | |
| subjects affected / exposed | 2 / 882 (0.23%) | 2 / 875 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sleep apnoea syndrome | | | |
| subjects affected / exposed | 2 / 882 (0.23%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stridor | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 2 / 875 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wheezing | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 882 (0.00%) | 2 / 875 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemoptysis | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonitis | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychiatric disorders | | | |
| Breath holding | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Restlessness | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Apathy | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Investigations | | | |
| Urine analysis abnormal | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Influenza virus test positive | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury, poisoning and procedural | | | |

| | | | |
|---|-----------------|-----------------|--|
| complications | | | |
| Fall | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Head injury | | | |
| subjects affected / exposed | 4 / 882 (0.45%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural haemorrhage | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skull fracture | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Burns second degree | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Exposure to toxic agent | | | |
| subjects affected / exposed | 3 / 882 (0.34%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foreign body | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Near drowning | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thermal burn | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 1 / 882 (0.11%) | 2 / 875 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skull fractured base | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laceration | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Accidental poisoning | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Contusion | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femur fracture | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hand fracture | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mouth injury | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative fever | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radius fracture | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Road traffic accident | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Congenital, familial and genetic disorders | | | |
| Ventricular septal defect | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |
| Cardiac failure congestive | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cyanosis | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| Cerebral infarction | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Convulsion | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|-----------------|-----------------|--|
| Febrile convulsion | | | |
| subjects affected / exposed | 7 / 882 (0.79%) | 8 / 875 (0.91%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fontanelle bulging | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypotonia | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Partial seizures | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Status epilepticus | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infantile spasms | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myoclonic epilepsy | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood and lymphatic system disorders | | | |
| Leukocytosis | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphadenitis | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 2 / 882 (0.23%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaemia | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye disorders | | | |
| Eye movement disorder | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Corneal perforation | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 2 / 882 (0.23%) | 3 / 875 (0.34%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intussusception | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 2 / 875 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oral disorder | | | |

| | | | |
|---|------------------|-----------------|--|
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vomiting | | | |
| subjects affected / exposed | 14 / 882 (1.59%) | 7 / 875 (0.80%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aphthous stomatitis | | | |
| subjects affected / exposed | 4 / 882 (0.45%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematemesis | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stomatitis | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Hepatomegaly | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Rash | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rash maculo-papular | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Henoch-Schonlein purpura | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rash macular | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Petechiae | | | |
| subjects affected / exposed | 2 / 882 (0.23%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pruritus | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal and urinary disorders | | | |
| Leukocyturia | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Kidney enlargement | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysuria | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |

| | | | |
|---|-----------------|-----------------|--|
| Trigger finger | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Monarthrititis | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Anal abscess | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacteraemia | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchiolitis | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis viral | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Croup infectious | | | |

| | | |
|---|------------------|------------------|
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Dysentery | | |
| subjects affected / exposed | 4 / 882 (0.45%) | 3 / 875 (0.34%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Gastroenteritis | | |
| subjects affected / exposed | 13 / 882 (1.47%) | 14 / 875 (1.60%) |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 14 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection | | |
| subjects affected / exposed | 3 / 882 (0.34%) | 1 / 875 (0.11%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Meningitis aseptic | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Meningitis viral | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Meningococcal infection | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Otitis media | | |
| subjects affected / exposed | 13 / 882 (1.47%) | 11 / 875 (1.26%) |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 11 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Otitis media acute | | |

| | | | |
|--|-----------------|-----------------|--|
| subjects affected / exposed | 1 / 882 (0.11%) | 3 / 875 (0.34%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pertussis | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pharyngitis | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia | | | |
| subjects affected / exposed | 9 / 882 (1.02%) | 5 / 875 (0.57%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative wound infection | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory syncytial virus bronchiolitis | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 2 / 875 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rotavirus infection | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Streptococcal bacteraemia | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 2 / 882 (0.23%) | 3 / 875 (0.34%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 2 / 882 (0.23%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral infection | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia urinary tract infection | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Exanthema subitum | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteomyelitis | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis rotavirus | | | |
| subjects affected / exposed | 2 / 882 (0.23%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Parainfluenzae virus infection | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Periorbital cellulitis | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumococcal bacteraemia | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia influenzal | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia viral | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Herpangina | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis bacterial | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cellulitis | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 1 / 882 (0.11%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Corynebacterium infection | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endophthalmitis | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| H1N1 influenza | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Influenza | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral discitis | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Localised infection | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia respiratory syncytial viral | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary tuberculosis | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinusitis | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tooth abscess | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound infection | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute tonsillitis | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 8 / 882 (0.91%) | 6 / 875 (0.69%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diet refusal | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lactose intolerance | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolic acidosis | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Weight gain poor | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Feeding disorder | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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

| Non-serious adverse events | Infant Series 13vPnC | Infant Series 7vPnC | After Infant Series 13vPnC |
|--|-------------------------|---------------------|-------------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 454 / 930 (48.82%) | 433 / 933 (46.41%) | 290 / 929 (31.22%) |
| Surgical and medical procedures | | | |
| Antibiotic prophylaxis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Inflammation | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Injection site erythema | | | |
| subjects affected / exposed | 4 / 930 (0.43%) | 2 / 933 (0.21%) | 0 / 929 (0.00%) |
| occurrences (all) | 4 | 2 | 0 |
| Injection site swelling | | | |

| | | | |
|--|---------------------------|---------------------------|------------------------|
| subjects affected / exposed occurrences (all) | 14 / 930 (1.51%) 14 | 10 / 933 (1.07%) 11 | 0 / 929 (0.00%) 0 |
| Pyrexia subjects affected / exposed occurrences (all) | 216 / 930 (23.23%) 279 | 194 / 933 (20.79%) 263 | 32 / 929 (3.44%) 33 |
| Developmental delay subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 1 / 929 (0.11%) 1 |
| Gait disturbance subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Oedema peripheral subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Chills subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Immune system disorders Food allergy subjects affected / exposed occurrences (all) | 1 / 930 (0.11%) 1 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders Choking subjects affected / exposed occurrences (all) | 1 / 930 (0.11%) 1 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Cough subjects affected / exposed occurrences (all) | 11 / 930 (1.18%) 11 | 4 / 933 (0.43%) 4 | 8 / 929 (0.86%) 8 |
| Lung infiltration subjects affected / exposed occurrences (all) | 1 / 930 (0.11%) 1 | 1 / 933 (0.11%) 1 | 1 / 929 (0.11%) 1 |
| Respiratory distress subjects affected / exposed occurrences (all) | 1 / 930 (0.11%) 1 | 2 / 933 (0.21%) 2 | 1 / 929 (0.11%) 1 |
| Sleep apnoea syndrome | | | |

| | | | |
|---|--------------------------|-------------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 1 / 933 (0.11%) 2 | 0 / 929 (0.00%) 0 |
| Stridor subjects affected / exposed occurrences (all) | 1 / 930 (0.11%) 1 | 2 / 933 (0.21%) 2 | 0 / 929 (0.00%) 0 |
| Wheezing subjects affected / exposed occurrences (all) | 1 / 930 (0.11%) 1 | 2 / 933 (0.21%) 2 | 1 / 929 (0.11%) 2 |
| Rhinorrhoea subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Asthma subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Pharyngeal erythema subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Pneumonitis subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Dyspnoea subjects affected / exposed occurrences (all) | 3 / 930 (0.32%) 3 | 0 / 933 (0.00%) 0 | 2 / 929 (0.22%) 2 |
| Psychiatric disorders Restlessness subjects affected / exposed occurrences (all) | 98 / 930 (10.54%) 125 | 89 / 933 (9.54%) 102 | 0 / 929 (0.00%) 0 |
| Apathy subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Investigations Laboratory test subjects affected / exposed occurrences (all) | 1 / 930 (0.11%) 1 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Urine analysis abnormal | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 3 / 930 (0.32%) 3 | 1 / 933 (0.11%) 1 | 1 / 929 (0.11%) 1 |
| White blood cells urine positive subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Injury, poisoning and procedural complications | | | |
| Limb injury | | | |
| subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 1 / 933 (0.11%) 1 | 0 / 929 (0.00%) 0 |
| Animal bite | | | |
| subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 1 / 929 (0.11%) 1 |
| Hand fracture | | | |
| subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Head injury | | | |
| subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Contusion | | | |
| subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Fracture | | | |
| subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Laceration | | | |
| subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Post procedural haemorrhage | | | |
| subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Postoperative fever | | | |
| subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Tooth fracture | | | |

| | | | |
|--|----------------------|----------------------|------------------------|
| subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Tooth injury subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Nervous system disorders | | | |
| Somnolence subjects affected / exposed occurrences (all) | 5 / 930 (0.54%) 5 | 1 / 933 (0.11%) 1 | 0 / 929 (0.00%) 0 |
| Nervous system disorder subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Febrile convulsion subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Blood and lymphatic system disorders | | | |
| Leukocytosis subjects affected / exposed occurrences (all) | 6 / 930 (0.65%) 6 | 9 / 933 (0.96%) 9 | 13 / 929 (1.40%) 13 |
| Lymphadenitis subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 1 / 929 (0.11%) 2 |
| Lymphadenopathy subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Leukopenia subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Neutropenia subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Ear and labyrinth disorders | | | |
| Tympanic membrane hyperaemia subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 1 / 929 (0.11%) 1 |
| Otorrhoea | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Eye disorders | | | |
| Conjunctivitis | | | |
| subjects affected / exposed | 2 / 930 (0.22%) | 1 / 933 (0.11%) | 0 / 929 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Eye swelling | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 16 / 930 (1.72%) | 9 / 933 (0.96%) | 13 / 929 (1.40%) |
| occurrences (all) | 16 | 9 | 14 |
| Vomiting | | | |
| subjects affected / exposed | 2 / 930 (0.22%) | 4 / 933 (0.43%) | 3 / 929 (0.32%) |
| occurrences (all) | 2 | 4 | 3 |
| Aphthous stomatitis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 1 / 929 (0.11%) |
| occurrences (all) | 0 | 0 | 1 |
| Constipation | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingivitis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cheilitis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematochezia | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Lip swelling subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Stomatitis subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Swollen tongue subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 1 / 933 (0.11%) 1 | 0 / 929 (0.00%) 0 |
| Dermatitis atopic subjects affected / exposed occurrences (all) | 1 / 930 (0.11%) 1 | 1 / 933 (0.11%) 1 | 0 / 929 (0.00%) 0 |
| Ingrowing nail subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 1 / 933 (0.11%) 1 | 0 / 929 (0.00%) 0 |
| Rash subjects affected / exposed occurrences (all) | 1 / 930 (0.11%) 1 | 1 / 933 (0.11%) 2 | 0 / 929 (0.00%) 0 |
| Seborrhoeic dermatitis subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Renal and urinary disorders | | | |
| Dysuria subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Vesicoureteric reflux subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders | | | |

| | | | |
|------------------------------------|-----------------|-----------------|-----------------|
| Monarthritis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Bacteraemia | | | |
| subjects affected / exposed | 5 / 930 (0.54%) | 3 / 933 (0.32%) | 2 / 929 (0.22%) |
| occurrences (all) | 5 | 3 | 2 |
| Bronchiolitis | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 3 / 933 (0.32%) | 1 / 929 (0.11%) |
| occurrences (all) | 1 | 3 | 1 |
| Bronchitis | | | |
| subjects affected / exposed | 2 / 930 (0.22%) | 5 / 933 (0.54%) | 1 / 929 (0.11%) |
| occurrences (all) | 2 | 5 | 1 |
| Cellulitis | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 5 / 933 (0.54%) | 1 / 929 (0.11%) |
| occurrences (all) | 1 | 5 | 1 |
| Dysentery | | | |
| subjects affected / exposed | 6 / 930 (0.65%) | 4 / 933 (0.43%) | 4 / 929 (0.43%) |
| occurrences (all) | 6 | 4 | 4 |
| Ear infection | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 1 / 933 (0.11%) | 3 / 929 (0.32%) |
| occurrences (all) | 1 | 1 | 5 |
| Infection | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 1 / 929 (0.11%) |
| occurrences (all) | 0 | 1 | 1 |
| Influenza | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 2 / 930 (0.22%) | 0 / 933 (0.00%) | 2 / 929 (0.22%) |
| occurrences (all) | 2 | 0 | 2 |
| Meningitis | | | |

| | | | |
|-----------------------------------|--------------------|--------------------|--------------------|
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 165 / 930 (17.74%) | 137 / 933 (14.68%) | 176 / 929 (18.95%) |
| occurrences (all) | 202 | 174 | 228 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 1 / 929 (0.11%) |
| occurrences (all) | 0 | 1 | 1 |
| Paronychia | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 16 / 930 (1.72%) | 14 / 933 (1.50%) | 21 / 929 (2.26%) |
| occurrences (all) | 16 | 14 | 24 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 1 / 933 (0.11%) | 1 / 929 (0.11%) |
| occurrences (all) | 0 | 1 | 1 |
| Tonsillitis | | | |
| subjects affected / exposed | 1 / 930 (0.11%) | 1 / 933 (0.11%) | 1 / 929 (0.11%) |
| occurrences (all) | 1 | 1 | 1 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 13 / 930 (1.40%) | 5 / 933 (0.54%) | 12 / 929 (1.29%) |
| occurrences (all) | 14 | 5 | 12 |
| Urinary tract infection | | | |
| subjects affected / exposed | 11 / 930 (1.18%) | 16 / 933 (1.71%) | 10 / 929 (1.08%) |
| occurrences (all) | 11 | 19 | 10 |
| Adenoiditis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anal abscess | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cellulitis orbital | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 1 / 929 (0.11%) |
| occurrences (all) | 0 | 0 | 1 |
| Hordeolum | | | |

| | | | |
|------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 1 / 929 (0.11%) |
| occurrences (all) | 0 | 0 | 2 |
| Impetigo | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 1 / 929 (0.11%) |
| occurrences (all) | 0 | 0 | 1 |
| Infectious mononucleosis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 1 / 929 (0.11%) |
| occurrences (all) | 0 | 0 | 1 |
| Localised infection | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 1 / 929 (0.11%) |
| occurrences (all) | 0 | 0 | 2 |
| Pertussis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 3 / 929 (0.32%) |
| occurrences (all) | 0 | 0 | 3 |
| Varicella | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 1 / 929 (0.11%) |
| occurrences (all) | 0 | 0 | 1 |
| Wound infection | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bullous impetigo | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand-foot-and-mouth disease | | | |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periorbital cellulitis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abscess | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acute tonsillitis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Brucellosis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erysipelas | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| External ear cellulitis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infected bites | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral infection | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Parotitis | | | |
| subjects affected / exposed | 0 / 930 (0.00%) | 0 / 933 (0.00%) | 0 / 929 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Scarlet fever | | | |

| | | | |
|--|------------------------|------------------------|------------------------|
| subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Skin infection subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Tooth abscess subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Tracheitis subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Vulvovaginal candidiasis subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Osteomyelitis subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 0 / 933 (0.00%) 0 | 0 / 929 (0.00%) 0 |
| Pharyngitis subjects affected / exposed occurrences (all) | 12 / 930 (1.29%) 13 | 24 / 933 (2.57%) 26 | 35 / 929 (3.77%) 37 |
| Metabolism and nutrition disorders Weight gain poor subjects affected / exposed occurrences (all) | 0 / 930 (0.00%) 0 | 1 / 933 (0.11%) 1 | 0 / 929 (0.00%) 0 |

| Non-serious adverse events | After Infant Series 7vPnC | Toddler Dose 13vPnC | Toddler Dose 7vPnC |
|---|------------------------------|------------------------|----------------------|
| Total subjects affected by non-serious adverse events subjects affected / exposed | 324 / 931 (34.80%) | 238 / 882 (26.98%) | 240 / 875 (27.43%) |
| Surgical and medical procedures Antibiotic prophylaxis subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| General disorders and administration site conditions Inflammation subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |

| | | | |
|--|------------------------|-------------------------|-------------------------|
| Injection site erythema subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 3 / 882 (0.34%) 3 | 1 / 875 (0.11%) 1 |
| Injection site swelling subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 6 / 882 (0.68%) 6 | 3 / 875 (0.34%) 3 |
| Pyrexia subjects affected / exposed occurrences (all) | 37 / 931 (3.97%) 39 | 90 / 882 (10.20%) 91 | 89 / 875 (10.17%) 90 |
| Developmental delay subjects affected / exposed occurrences (all) | 2 / 931 (0.21%) 2 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Gait disturbance subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 1 / 882 (0.11%) 1 | 0 / 875 (0.00%) 0 |
| Oedema peripheral subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 1 / 882 (0.11%) 1 | 1 / 875 (0.11%) 1 |
| Chills subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Immune system disorders Food allergy subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders Choking subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Cough subjects affected / exposed occurrences (all) | 10 / 931 (1.07%) 11 | 4 / 882 (0.45%) 4 | 1 / 875 (0.11%) 1 |
| Lung infiltration subjects affected / exposed occurrences (all) | 3 / 931 (0.32%) 3 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Respiratory distress | | | |

| | | | |
|-----------------------------|-----------------|------------------|------------------|
| subjects affected / exposed | 1 / 931 (0.11%) | 1 / 882 (0.11%) | 0 / 875 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Sleep apnoea syndrome | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stridor | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wheezing | | | |
| subjects affected / exposed | 4 / 931 (0.43%) | 1 / 882 (0.11%) | 0 / 875 (0.00%) |
| occurrences (all) | 5 | 1 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 1 / 882 (0.11%) | 0 / 875 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pharyngeal erythema | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspnoea | | | |
| subjects affected / exposed | 2 / 931 (0.21%) | 0 / 882 (0.00%) | 1 / 875 (0.11%) |
| occurrences (all) | 3 | 0 | 1 |
| Psychiatric disorders | | | |
| Restlessness | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 11 / 882 (1.25%) | 11 / 875 (1.26%) |
| occurrences (all) | 0 | 11 | 11 |
| Apathy | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Investigations | | | |
| Laboratory test | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Urine analysis abnormal subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| White blood cells urine positive subjects affected / exposed occurrences (all) | 1 / 931 (0.11%) 1 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Injury, poisoning and procedural complications | | | |
| Limb injury subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Animal bite subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Hand fracture subjects affected / exposed occurrences (all) | 1 / 931 (0.11%) 1 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Head injury subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 1 / 875 (0.11%) 1 |
| Contusion subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Fracture subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Laceration subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Post procedural haemorrhage subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Postoperative fever | | | |

| | | | |
|--|------------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Tooth fracture subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Tooth injury subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Nervous system disorders Somnolence subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Nervous system disorder subjects affected / exposed occurrences (all) | 1 / 931 (0.11%) 1 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Febrile convulsion subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Blood and lymphatic system disorders Leukocytosis subjects affected / exposed occurrences (all) | 17 / 931 (1.83%) 19 | 4 / 882 (0.45%) 4 | 4 / 875 (0.46%) 4 |
| Lymphadenitis subjects affected / exposed occurrences (all) | 1 / 931 (0.11%) 1 | 0 / 882 (0.00%) 0 | 1 / 875 (0.11%) 1 |
| Lymphadenopathy subjects affected / exposed occurrences (all) | 1 / 931 (0.11%) 1 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Leukopenia subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Neutropenia subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Ear and labyrinth disorders | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| Tympanic membrane hyperaemia subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Otorrhoea subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Eye disorders | | | |
| Conjunctivitis subjects affected / exposed occurrences (all) | 2 / 931 (0.21%) 2 | 0 / 882 (0.00%) 0 | 1 / 875 (0.11%) 1 |
| Eye swelling subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Diarrhoea subjects affected / exposed occurrences (all) | 8 / 931 (0.86%) 8 | 4 / 882 (0.45%) 4 | 7 / 875 (0.80%) 7 |
| Vomiting subjects affected / exposed occurrences (all) | 2 / 931 (0.21%) 2 | 1 / 882 (0.11%) 1 | 3 / 875 (0.34%) 3 |
| Aphthous stomatitis subjects affected / exposed occurrences (all) | 2 / 931 (0.21%) 2 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Constipation subjects affected / exposed occurrences (all) | 1 / 931 (0.11%) 1 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Gingivitis subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 1 / 875 (0.11%) 1 |
| Rectal haemorrhage subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 1 / 882 (0.11%) 1 | 0 / 875 (0.00%) 0 |
| Cheilitis | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Haematochezia subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Lip swelling subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Stomatitis subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Swollen tongue subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis subjects affected / exposed occurrences (all) | 1 / 931 (0.11%) 1 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Dermatitis atopic subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Ingrowing nail subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Rash subjects affected / exposed occurrences (all) | 1 / 931 (0.11%) 1 | 2 / 882 (0.23%) 2 | 2 / 875 (0.23%) 2 |
| Seborrhoeic dermatitis subjects affected / exposed occurrences (all) | 1 / 931 (0.11%) 1 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Renal and urinary disorders | | | |
| Dysuria subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Vesicoureteric reflux | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Monarthritis | | | |
| subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Infections and infestations | | | |
| Bacteraemia | | | |
| subjects affected / exposed occurrences (all) | 3 / 931 (0.32%) 3 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Bronchiolitis | | | |
| subjects affected / exposed occurrences (all) | 1 / 931 (0.11%) 2 | 0 / 882 (0.00%) 0 | 3 / 875 (0.34%) 4 |
| Bronchitis | | | |
| subjects affected / exposed occurrences (all) | 2 / 931 (0.21%) 2 | 1 / 882 (0.11%) 1 | 1 / 875 (0.11%) 1 |
| Cellulitis | | | |
| subjects affected / exposed occurrences (all) | 1 / 931 (0.11%) 1 | 1 / 882 (0.11%) 1 | 2 / 875 (0.23%) 2 |
| Dysentery | | | |
| subjects affected / exposed occurrences (all) | 6 / 931 (0.64%) 7 | 1 / 882 (0.11%) 1 | 1 / 875 (0.11%) 1 |
| Ear infection | | | |
| subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Gastroenteritis | | | |
| subjects affected / exposed occurrences (all) | 3 / 931 (0.32%) 3 | 2 / 882 (0.23%) 2 | 0 / 875 (0.00%) 0 |
| Infection | | | |
| subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 1 / 875 (0.11%) 1 |
| Influenza | | | |
| subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Lower respiratory tract infection | | | |

| | | | |
|-----------------------------------|--------------------|-------------------|-------------------|
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 1 / 875 (0.11%) |
| occurrences (all) | 0 | 0 | 1 |
| Meningitis | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 195 / 931 (20.95%) | 93 / 882 (10.54%) | 92 / 875 (10.51%) |
| occurrences (all) | 235 | 102 | 102 |
| Otitis media acute | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 25 / 931 (2.69%) | 7 / 882 (0.79%) | 13 / 875 (1.49%) |
| occurrences (all) | 25 | 7 | 13 |
| Rhinitis | | | |
| subjects affected / exposed | 4 / 931 (0.43%) | 1 / 882 (0.11%) | 0 / 875 (0.00%) |
| occurrences (all) | 4 | 1 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 2 / 875 (0.23%) |
| occurrences (all) | 1 | 0 | 2 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 15 / 931 (1.61%) | 2 / 882 (0.23%) | 11 / 875 (1.26%) |
| occurrences (all) | 17 | 2 | 12 |
| Urinary tract infection | | | |
| subjects affected / exposed | 5 / 931 (0.54%) | 2 / 882 (0.23%) | 3 / 875 (0.34%) |
| occurrences (all) | 6 | 2 | 4 |
| Adenoiditis | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Anal abscess | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 1 / 875 (0.11%) |
| occurrences (all) | 2 | 0 | 1 |
| Cellulitis orbital | | | |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hordeolum | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Impetigo | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 1 / 882 (0.11%) | 0 / 875 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Infectious mononucleosis | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Localised infection | | | |
| subjects affected / exposed | 2 / 931 (0.21%) | 0 / 882 (0.00%) | 1 / 875 (0.11%) |
| occurrences (all) | 2 | 0 | 1 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pertussis | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 2 / 931 (0.21%) | 0 / 882 (0.00%) | 1 / 875 (0.11%) |
| occurrences (all) | 2 | 0 | 1 |
| Sinusitis | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Varicella | | | |
| subjects affected / exposed | 1 / 931 (0.11%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 931 (0.00%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wound infection | | | |
| subjects affected / exposed | 2 / 931 (0.21%) | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Bullous impetigo | | | |

| | | | |
|---|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 1 / 875 (0.11%) 1 |
| Hand-foot-and-mouth disease subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 1 / 875 (0.11%) 1 |
| Oral candidiasis subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 1 / 875 (0.11%) 1 |
| Periorbital cellulitis subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 2 / 882 (0.23%) 2 | 0 / 875 (0.00%) 0 |
| Subcutaneous abscess subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 1 / 875 (0.11%) 1 |
| Abscess subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Acute tonsillitis subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Brucellosis subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Erysipelas subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| External ear cellulitis subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Infected bites subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Oral infection subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Parotitis | | | |

| | | | |
|--|------------------------|------------------------|------------------------|
| subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Scarlet fever subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Skin infection subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Tooth abscess subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Tracheitis subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Vulvovaginal candidiasis subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Osteomyelitis subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |
| Pharyngitis subjects affected / exposed occurrences (all) | 32 / 931 (3.44%) 34 | 34 / 882 (3.85%) 34 | 27 / 875 (3.09%) 27 |
| Metabolism and nutrition disorders Weight gain poor subjects affected / exposed occurrences (all) | 0 / 931 (0.00%) 0 | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 |

| Non-serious adverse events | After Toddler Dose 13vPnC | After Toddler Dose 7vPnC | |
|---|------------------------------|-----------------------------|--|
| Total subjects affected by non-serious adverse events subjects affected / exposed | 462 / 882 (52.38%) | 455 / 875 (52.00%) | |
| Surgical and medical procedures Antibiotic prophylaxis subjects affected / exposed occurrences (all) | 0 / 882 (0.00%) 0 | 1 / 875 (0.11%) 1 | |
| General disorders and administration site conditions | | | |

| | | | |
|---|------------------|------------------|--|
| Inflammation | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Injection site erythema | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Injection site swelling | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Pyrexia | | | |
| subjects affected / exposed | 64 / 882 (7.26%) | 68 / 875 (7.77%) | |
| occurrences (all) | 71 | 71 | |
| Developmental delay | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Gait disturbance | | | |
| subjects affected / exposed | 2 / 882 (0.23%) | 0 / 875 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Chills | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Immune system disorders | | | |
| Food allergy | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Choking | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Cough | | | |
| subjects affected / exposed | 31 / 882 (3.51%) | 20 / 875 (2.29%) | |
| occurrences (all) | 33 | 23 | |
| Lung infiltration | | | |

| | | | |
|-----------------------------|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 882 (0.00%) | 2 / 875 (0.23%) | |
| occurrences (all) | 0 | 2 | |
| Respiratory distress | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 3 / 875 (0.34%) | |
| occurrences (all) | 0 | 3 | |
| Sleep apnoea syndrome | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Stridor | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences (all) | 0 | 1 | |
| Wheezing | | | |
| subjects affected / exposed | 3 / 882 (0.34%) | 3 / 875 (0.34%) | |
| occurrences (all) | 3 | 3 | |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Asthma | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences (all) | 0 | 1 | |
| Pharyngeal erythema | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pneumonitis | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Dyspnoea | | | |
| subjects affected / exposed | 3 / 882 (0.34%) | 2 / 875 (0.23%) | |
| occurrences (all) | 3 | 2 | |
| Psychiatric disorders | | | |
| Restlessness | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Apathy | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences (all) | 0 | 1 | |

| | | | |
|--|-----------------|-----------------|--|
| Investigations | | | |
| Laboratory test | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Urine analysis abnormal | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences (all) | 0 | 1 | |
| White blood cells urine positive | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Injury, poisoning and procedural complications | | | |
| Limb injury | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences (all) | 0 | 1 | |
| Animal bite | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences (all) | 0 | 1 | |
| Hand fracture | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Head injury | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Contusion | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Fracture | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Laceration | | | |
| subjects affected / exposed | 2 / 882 (0.23%) | 1 / 875 (0.11%) | |
| occurrences (all) | 2 | 1 | |
| Post procedural haemorrhage | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences (all) | 0 | 1 | |
| Postoperative fever | | | |

| | | | |
|---|------------------------|------------------------|--|
| subjects affected / exposed occurrences (all) | 1 / 882 (0.11%) 1 | 0 / 875 (0.00%) 0 | |
| Tooth fracture subjects affected / exposed occurrences (all) | 1 / 882 (0.11%) 1 | 0 / 875 (0.00%) 0 | |
| Tooth injury subjects affected / exposed occurrences (all) | 1 / 882 (0.11%) 1 | 0 / 875 (0.00%) 0 | |
| Nervous system disorders | | | |
| Somnolence subjects affected / exposed occurrences (all) | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 | |
| Nervous system disorder subjects affected / exposed occurrences (all) | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 | |
| Febrile convulsion subjects affected / exposed occurrences (all) | 1 / 882 (0.11%) 1 | 1 / 875 (0.11%) 1 | |
| Blood and lymphatic system disorders | | | |
| Leukocytosis subjects affected / exposed occurrences (all) | 15 / 882 (1.70%) 15 | 15 / 875 (1.71%) 16 | |
| Lymphadenitis subjects affected / exposed occurrences (all) | 3 / 882 (0.34%) 3 | 2 / 875 (0.23%) 2 | |
| Lymphadenopathy subjects affected / exposed occurrences (all) | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 | |
| Leukopenia subjects affected / exposed occurrences (all) | 0 / 882 (0.00%) 0 | 1 / 875 (0.11%) 1 | |
| Neutropenia subjects affected / exposed occurrences (all) | 0 / 882 (0.00%) 0 | 1 / 875 (0.11%) 2 | |
| Ear and labyrinth disorders | | | |

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|--|------------------------|------------------------|--|
| Tympanic membrane hyperaemia subjects affected / exposed occurrences (all) | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 | |
| Otorrhoea subjects affected / exposed occurrences (all) | 1 / 882 (0.11%) 1 | 0 / 875 (0.00%) 0 | |
| Eye disorders | | | |
| Conjunctivitis subjects affected / exposed occurrences (all) | 1 / 882 (0.11%) 1 | 4 / 875 (0.46%) 4 | |
| Eye swelling subjects affected / exposed occurrences (all) | 0 / 882 (0.00%) 0 | 1 / 875 (0.11%) 1 | |
| Gastrointestinal disorders | | | |
| Abdominal pain subjects affected / exposed occurrences (all) | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 | |
| Diarrhoea subjects affected / exposed occurrences (all) | 25 / 882 (2.83%) 25 | 34 / 875 (3.89%) 37 | |
| Vomiting subjects affected / exposed occurrences (all) | 13 / 882 (1.47%) 13 | 8 / 875 (0.91%) 8 | |
| Aphthous stomatitis subjects affected / exposed occurrences (all) | 1 / 882 (0.11%) 1 | 2 / 875 (0.23%) 2 | |
| Constipation subjects affected / exposed occurrences (all) | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 | |
| Gingivitis subjects affected / exposed occurrences (all) | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 | |
| Rectal haemorrhage subjects affected / exposed occurrences (all) | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 | |
| Cheilitis | | | |

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|--|----------------------|----------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 882 (0.00%) 0 | 1 / 875 (0.11%) 1 | |
| Haematochezia subjects affected / exposed occurrences (all) | 0 / 882 (0.00%) 0 | 1 / 875 (0.11%) 2 | |
| Lip swelling subjects affected / exposed occurrences (all) | 0 / 882 (0.00%) 0 | 1 / 875 (0.11%) 1 | |
| Stomatitis subjects affected / exposed occurrences (all) | 2 / 882 (0.23%) 2 | 0 / 875 (0.00%) 0 | |
| Swollen tongue subjects affected / exposed occurrences (all) | 0 / 882 (0.00%) 0 | 1 / 875 (0.11%) 1 | |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis subjects affected / exposed occurrences (all) | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 | |
| Dermatitis atopic subjects affected / exposed occurrences (all) | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 | |
| Ingrowing nail subjects affected / exposed occurrences (all) | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 | |
| Rash subjects affected / exposed occurrences (all) | 2 / 882 (0.23%) 2 | 1 / 875 (0.11%) 1 | |
| Seborrhoeic dermatitis subjects affected / exposed occurrences (all) | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 | |
| Renal and urinary disorders | | | |
| Dysuria subjects affected / exposed occurrences (all) | 1 / 882 (0.11%) 1 | 0 / 875 (0.00%) 0 | |
| Vesicoureteric reflux | | | |

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|---|------------------------|------------------------|--|
| subjects affected / exposed occurrences (all) | 1 / 882 (0.11%) 1 | 0 / 875 (0.00%) 0 | |
| Musculoskeletal and connective tissue disorders Monarthritis subjects affected / exposed occurrences (all) | 0 / 882 (0.00%) 0 | 1 / 875 (0.11%) 1 | |
| Infections and infestations Bacteraemia subjects affected / exposed occurrences (all) | 1 / 882 (0.11%) 1 | 5 / 875 (0.57%) 5 | |
| Bronchiolitis subjects affected / exposed occurrences (all) | 5 / 882 (0.57%) 5 | 13 / 875 (1.49%) 14 | |
| Bronchitis subjects affected / exposed occurrences (all) | 9 / 882 (1.02%) 10 | 10 / 875 (1.14%) 10 | |
| Cellulitis subjects affected / exposed occurrences (all) | 6 / 882 (0.68%) 6 | 5 / 875 (0.57%) 6 | |
| Dysentery subjects affected / exposed occurrences (all) | 10 / 882 (1.13%) 10 | 13 / 875 (1.49%) 14 | |
| Ear infection subjects affected / exposed occurrences (all) | 0 / 882 (0.00%) 0 | 0 / 875 (0.00%) 0 | |
| Gastroenteritis subjects affected / exposed occurrences (all) | 7 / 882 (0.79%) 7 | 3 / 875 (0.34%) 3 | |
| Infection subjects affected / exposed occurrences (all) | 3 / 882 (0.34%) 3 | 2 / 875 (0.23%) 5 | |
| Influenza subjects affected / exposed occurrences (all) | 1 / 882 (0.11%) 1 | 0 / 875 (0.00%) 0 | |
| Lower respiratory tract infection | | | |

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|-----------------------------------|--------------------|--------------------|
| subjects affected / exposed | 2 / 882 (0.23%) | 4 / 875 (0.46%) |
| occurrences (all) | 2 | 4 |
| Meningitis | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 0 | 0 |
| Otitis media | | |
| subjects affected / exposed | 267 / 882 (30.27%) | 246 / 875 (28.11%) |
| occurrences (all) | 419 | 391 |
| Otitis media acute | | |
| subjects affected / exposed | 2 / 882 (0.23%) | 2 / 875 (0.23%) |
| occurrences (all) | 2 | 3 |
| Paronychia | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 0 | 0 |
| Pneumonia | | |
| subjects affected / exposed | 57 / 882 (6.46%) | 58 / 875 (6.63%) |
| occurrences (all) | 61 | 65 |
| Rhinitis | | |
| subjects affected / exposed | 7 / 882 (0.79%) | 2 / 875 (0.23%) |
| occurrences (all) | 7 | 2 |
| Tonsillitis | | |
| subjects affected / exposed | 9 / 882 (1.02%) | 13 / 875 (1.49%) |
| occurrences (all) | 9 | 14 |
| Upper respiratory tract infection | | |
| subjects affected / exposed | 37 / 882 (4.20%) | 43 / 875 (4.91%) |
| occurrences (all) | 44 | 55 |
| Urinary tract infection | | |
| subjects affected / exposed | 10 / 882 (1.13%) | 6 / 875 (0.69%) |
| occurrences (all) | 14 | 6 |
| Adenoiditis | | |
| subjects affected / exposed | 3 / 882 (0.34%) | 0 / 875 (0.00%) |
| occurrences (all) | 3 | 0 |
| Anal abscess | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 0 | 0 |
| Cellulitis orbital | | |

| | | |
|-----------------------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 882 (0.11%) | 1 / 875 (0.11%) |
| occurrences (all) | 1 | 1 |
| Hordeolum | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 0 | 0 |
| Impetigo | | |
| subjects affected / exposed | 2 / 882 (0.23%) | 6 / 875 (0.69%) |
| occurrences (all) | 2 | 6 |
| Infectious mononucleosis | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) |
| occurrences (all) | 1 | 0 |
| Localised infection | | |
| subjects affected / exposed | 3 / 882 (0.34%) | 0 / 875 (0.00%) |
| occurrences (all) | 3 | 0 |
| Nasopharyngitis | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) |
| occurrences (all) | 1 | 0 |
| Pertussis | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 0 | 0 |
| Respiratory tract infection | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 0 | 0 |
| Sinusitis | | |
| subjects affected / exposed | 2 / 882 (0.23%) | 2 / 875 (0.23%) |
| occurrences (all) | 2 | 2 |
| Varicella | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 0 | 0 |
| Viral infection | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 3 / 875 (0.34%) |
| occurrences (all) | 1 | 3 |
| Wound infection | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 1 / 875 (0.11%) |
| occurrences (all) | 1 | 1 |
| Bullous impetigo | | |

| | | |
|-----------------------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 0 | 0 |
| Hand-foot-and-mouth disease | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 0 | 0 |
| Oral candidiasis | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) |
| occurrences (all) | 0 | 0 |
| Periorbital cellulitis | | |
| subjects affected / exposed | 5 / 882 (0.57%) | 3 / 875 (0.34%) |
| occurrences (all) | 5 | 3 |
| Subcutaneous abscess | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) |
| occurrences (all) | 0 | 1 |
| Abscess | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) |
| occurrences (all) | 0 | 1 |
| Acute tonsillitis | | |
| subjects affected / exposed | 4 / 882 (0.45%) | 3 / 875 (0.34%) |
| occurrences (all) | 4 | 4 |
| Brucellosis | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) |
| occurrences (all) | 0 | 1 |
| Erysipelas | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) |
| occurrences (all) | 1 | 0 |
| External ear cellulitis | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) |
| occurrences (all) | 1 | 0 |
| Infected bites | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) |
| occurrences (all) | 0 | 1 |
| Oral infection | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) |
| occurrences (all) | 0 | 1 |
| Parotitis | | |

| | | | |
|------------------------------------|--------------------|--------------------|--|
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Scarlet fever | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 2 / 875 (0.23%) | |
| occurrences (all) | 1 | 2 | |
| Skin infection | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 2 / 875 (0.23%) | |
| occurrences (all) | 0 | 2 | |
| Tooth abscess | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Tracheitis | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 1 / 875 (0.11%) | |
| occurrences (all) | 0 | 1 | |
| Vulvovaginal candidiasis | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Osteomyelitis | | | |
| subjects affected / exposed | 1 / 882 (0.11%) | 0 / 875 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pharyngitis | | | |
| subjects affected / exposed | 112 / 882 (12.70%) | 114 / 875 (13.03%) | |
| occurrences (all) | 134 | 134 | |
| Metabolism and nutrition disorders | | | |
| Weight gain poor | | | |
| subjects affected / exposed | 0 / 882 (0.00%) | 0 / 875 (0.00%) | |
| occurrences (all) | 0 | 0 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-----------------|---|
| 11 January 2008 | 1- AEs associated with antibiotic use were to be summarized. 2- Enterally administered vaccines given at any time were added as a permitted treatment. |
| 16 April 2008 | 1- Topical antibiotics were excluded as a type of antibiotic use to be considered when AEs associated antibiotic use were to be summarized and for the criterion for temporarily delaying vaccine administration due to antibiotic use. 2- Live vaccines administered by the parenteral route were allowed to be given on the same day as the study vaccine. |
| 24 July 2008 | The randomization procedure was modified to use new treatment codes after the shipping error. Subjects enrolled with the first set of treatment codes were designated cohort 1 and the subjects enrolled with the second set of treatment codes were designated cohort 2. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Study designated analysis of effect of 13vPnC on serotypes 6A+19A, changed prior to unblinding, to effect on 6A'+19A. Serotype 6A found to include serotype 6A isolates and isolates of newly identified serotype 6C. Serotype 6A assessed as 6A+6C (6A').

Notes: