



Clinical trial results:

A Phase 3, Open Label Trial Evaluating the Safety, Tolerability and Immunogenicity of 13-valent Pneumococcal Conjugate Vaccine in Healthy Children Aged 15 Months to 17 Years in the United States

Due to a system error, the data reported in v1 is not correct and has been removed from public view.

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2009-017304-88 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 10 August 2010 |

Results information

| | |
|--------------------------------|---|
| Result version number | v2 (current) |
| This version publication date | 28 July 2016 |
| First version publication date | 01 August 2015 |
| Version creation reason | • Correction of full data set reporting periods and duplicate AEs in their data |

Trial information

Trial identification

| | |
|-----------------------|-------------|
| Sponsor protocol code | 6096A1-3011 |
|-----------------------|-------------|

Additional study identifiers

| | |
|------------------------------------|--------------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT00761631 |
| WHO universal trial number (UTN) | - |
| Other trial identifiers | Alias ID: B1851010 |

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

| | |
|--|----------------|
| Analysis stage | Final |
| Date of interim/final analysis | 07 March 2012 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 10 August 2010 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

1-To assess the pneumococcal immune responses induced by 13-valent pneumococcal conjugate vaccine (13vPnC) when measured 1 month after the last scheduled dose of 13vPnC in each of 4 age groups.
2- To evaluate the acceptability of the safety profile of 13vPnC as measured by the incidence rates of local reactions, systemic events, and AEs. This objective is applicable to all 4 groups and both cohorts.

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 | 18 November 2008 |
| Long term follow-up planned | Yes |
| Long term follow-up rationale | Safety |
| Long term follow-up duration | 6 Months |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|---------------------|
| Country: Number of subjects enrolled | United States: 1200 |
| Worldwide total number of subjects | 1200 |
| 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) | 302 |
| Children (2-11 years) | 671 |
| Adolescents (12-17 years) | 227 |
| 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:

Subjects were stratified by age group. Group 1 included subjects aged greater than (>) 15 months to less than (<) 2 years. Group 2 included subjects aged greater than or equal to (>=) 2 to <5 years. Group 3 included subjects aged >=5 to <10 years. Group 4 included subjects aged >=10 to <18 years.

Period 1

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

Arms

| | |
|------------------------------|---------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | 13vPnC Group 1 (Cohort 1) |

Arm description:

13vPnC administered at baseline and anytime from Day 56 to Day 70 for a total of 2 doses. Subjects must have previously received at least 3 doses of 7-valent pneumococcal conjugate vaccine (7vPnC). Includes subjects enrolled prior to protocol amendment to increase sample size (Cohort 1).

| | |
|--|-------------------|
| 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 baseline and anytime from Day 56 to Day 70 for a total of 2 doses.

| | |
|------------------|---------------------------|
| Arm title | 13vPnC Group 2 (Cohort 1) |
|------------------|---------------------------|

Arm description:

13vPnC administered at baseline. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled prior to protocol amendment to increase sample size (Cohort 1).

| | |
|--|-------------------|
| 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 13vPnC 0.5 mL dose at baseline.

| | |
|------------------|---------------------------|
| Arm title | 13vPnC Group 1 (Cohort 2) |
|------------------|---------------------------|

Arm description:

13vPnC administered at baseline and anytime from Day 56 to Day 70 for a total of 2 doses. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled after protocol amendment to increase sample size (Cohort 2).

| | |
|----------|--------------|
| 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 dose at baseline and anytime from Day 56 to Day 70 for a total of 2 doses.

| | |
|------------------|---------------------------|
| Arm title | 13vPnC Group 2 (Cohort 2) |
|------------------|---------------------------|

Arm description:

13vPnC administered at baseline. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled after protocol amendment to increase sample size (Cohort 2).

| | |
|--|-------------------|
| 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 baseline.

| | |
|------------------|----------------|
| Arm title | 13vPnC Group 3 |
|------------------|----------------|

Arm description:

13vPnC administered at baseline. Subjects must have previously received at least 1 dose of 7vPnC.

| | |
|--|-------------------|
| 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 baseline.

| | |
|------------------|----------------|
| Arm title | 13vPnC Group 4 |
|------------------|----------------|

Arm description:

13vPnC administered at baseline. Subjects must not have received 7vPnC or any other pneumococcal vaccine.

| | |
|--|-------------------|
| 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 baseline.

| Number of subjects in period 1 | 13vPnC Group 1 (Cohort 1) | 13vPnC Group 2 (Cohort 1) | 13vPnC Group 1 (Cohort 2) |
|--------------------------------|------------------------------|------------------------------|------------------------------|
| Started | 126 | 181 | 176 |
| Vaccinated Dose 1 | 124 | 179 | 175 |
| Vaccinated Dose 2 | 112 | 0 ^[1] | 165 |
| Completed | 111 | 174 | 160 |
| Not completed | 15 | 7 | 16 |
| Physician decision | 1 | - | - |
| Failed to return | 1 | - | 1 |
| Parent/legal guardian request | 8 | 3 | 8 |
| Unspecified | - | - | - |
| Lost to follow-up | 2 | 4 | 7 |
| Randomized, not treated | 1 | - | - |
| Protocol deviation | 2 | - | - |

| Number of subjects in period 1 | 13vPnC Group 2 (Cohort 2) | 13vPnC Group 3 | 13vPnC Group 4 |
|--------------------------------|------------------------------|------------------|------------------|
| Started | 119 | 299 | 299 |
| Vaccinated Dose 1 | 118 | 294 | 298 |
| Vaccinated Dose 2 | 0 ^[2] | 0 ^[3] | 0 ^[4] |
| Completed | 116 | 277 | 294 |
| Not completed | 3 | 22 | 5 |
| Physician decision | - | - | - |
| Failed to return | 1 | 5 | 2 |
| Parent/legal guardian request | - | 5 | - |
| Unspecified | - | 1 | 1 |
| Lost to follow-up | 1 | 6 | 1 |
| Randomized, not treated | - | - | - |
| Protocol deviation | 1 | 5 | 1 |

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Subjects in 13vPnC Group 2 were planned to receive only dose 1 of 13vPnC.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Subjects in 13vPnC Group 2 were planned to receive only dose 1 of 13vPnC.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Subjects in 13vPnC Group 3 were planned to receive only dose 1 of 13vPnC.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Subjects in 13vPnC Group 4 were planned to receive only dose 1 of 13vPnC.

Baseline characteristics

Reporting groups

| | |
|------------------------------|--|
| Reporting group title | 13vPnC Group 1 (Cohort 1) |
| Reporting group description: | 13vPnC administered at baseline and anytime from Day 56 to Day 70 for a total of 2 doses. Subjects must have previously received at least 3 doses of 7-valent pneumococcal conjugate vaccine (7vPnC). Includes subjects enrolled prior to protocol amendment to increase sample size (Cohort 1). |
| Reporting group title | 13vPnC Group 2 (Cohort 1) |
| Reporting group description: | 13vPnC administered at baseline. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled prior to protocol amendment to increase sample size (Cohort 1). |
| Reporting group title | 13vPnC Group 1 (Cohort 2) |
| Reporting group description: | 13vPnC administered at baseline and anytime from Day 56 to Day 70 for a total of 2 doses. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled after protocol amendment to increase sample size (Cohort 2). |
| Reporting group title | 13vPnC Group 2 (Cohort 2) |
| Reporting group description: | 13vPnC administered at baseline. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled after protocol amendment to increase sample size (Cohort 2). |
| Reporting group title | 13vPnC Group 3 |
| Reporting group description: | 13vPnC administered at baseline. Subjects must have previously received at least 1 dose of 7vPnC. |
| Reporting group title | 13vPnC Group 4 |
| Reporting group description: | 13vPnC administered at baseline. Subjects must not have received 7vPnC or any other pneumococcal vaccine. |

| Reporting group values | 13vPnC Group 1 (Cohort 1) | 13vPnC Group 2 (Cohort 1) | 13vPnC Group 1 (Cohort 2) |
|--|------------------------------|------------------------------|------------------------------|
| Number of subjects | 126 | 181 | 176 |
| Age categorical Units: Subjects | | | |
| Infants and toddlers (28 days-23 months) | 126 | 0 | 176 |
| Children (2-11 years) | 0 | 181 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Gender categorical Units: Subjects | | | |
| Female | 65 | 74 | 83 |
| Male | 61 | 107 | 93 |

| Reporting group values | 13vPnC Group 2 (Cohort 2) | 13vPnC Group 3 | 13vPnC Group 4 |
|--|------------------------------|----------------|----------------|
| Number of subjects | 119 | 299 | 299 |
| Age categorical Units: Subjects | | | |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 119 | 299 | 72 |
| Adolescents (12-17 years) | 0 | 0 | 227 |

| | | | |
|---------------------------------------|----|-----|-----|
| Gender categorical Units: Subjects | | | |
| Female | 65 | 155 | 136 |
| Male | 54 | 144 | 163 |

| | | | |
|--|-------|--|--|
| Reporting group values | Total | | |
| Number of subjects | 1200 | | |
| Age categorical Units: Subjects | | | |
| Infants and toddlers (28 days-23 months) | 302 | | |
| Children (2-11 years) | 671 | | |
| Adolescents (12-17 years) | 227 | | |
| Gender categorical Units: Subjects | | | |
| Female | 578 | | |
| Male | 622 | | |

End points

End points reporting groups

| | |
|--|---------------------------|
| Reporting group title | 13vPnC Group 1 (Cohort 1) |
| Reporting group description: 13vPnC administered at baseline and anytime from Day 56 to Day 70 for a total of 2 doses. Subjects must have previously received at least 3 doses of 7-valent pneumococcal conjugate vaccine (7vPnC). Includes subjects enrolled prior to protocol amendment to increase sample size (Cohort 1). | |
| Reporting group title | 13vPnC Group 2 (Cohort 1) |
| Reporting group description: 13vPnC administered at baseline. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled prior to protocol amendment to increase sample size (Cohort 1). | |
| Reporting group title | 13vPnC Group 1 (Cohort 2) |
| Reporting group description: 13vPnC administered at baseline and anytime from Day 56 to Day 70 for a total of 2 doses. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled after protocol amendment to increase sample size (Cohort 2). | |
| Reporting group title | 13vPnC Group 2 (Cohort 2) |
| Reporting group description: 13vPnC administered at baseline. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled after protocol amendment to increase sample size (Cohort 2). | |
| Reporting group title | 13vPnC Group 3 |
| Reporting group description: 13vPnC administered at baseline. Subjects must have previously received at least 1 dose of 7vPnC. | |
| Reporting group title | 13vPnC Group 4 |
| Reporting group description: 13vPnC administered at baseline. Subjects must not have received 7vPnC or any other pneumococcal vaccine. | |

Primary: Percentage of Subjects Achieving Predefined Serotype-specific Immunoglobulin G (IgG) Antibody Concentration Greater Than or Equal to (\geq) 0.35 Micrograms Per Milliliter (Mcg/mL) Measured 1 Month After Vaccination in Group 1 and 2

| | |
|--|---|
| End point title | Percentage of Subjects Achieving Predefined Serotype-specific Immunoglobulin G (IgG) Antibody Concentration Greater Than or Equal to (\geq) 0.35 Micrograms Per Milliliter (Mcg/mL) Measured 1 Month After Vaccination in Group 1 and 2 ^{[1][2]} |
| End point description: Percentage of subjects achieving world health organization (WHO) predefined antibody threshold ≥ 0.35 mcg/mL along with the corresponding 95% confidence interval (CI) for the 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (serotypes 1, 3, 5, 6A, 7F, and 19A) were presented. Exact 2-sided CI based on observed proportion of subjects. Evaluable Immunogenicity Population (EIP): all subjects who met all inclusion criteria, received all assigned doses of study vaccine, had at least 1 valid and determinate assay result from blood draw within 27-56 days after last scheduled vaccination for proposed analysis and no major protocol violations. | |
| End point type | Primary |
| End point timeframe: 28 to 42 days after dose 2 for Group 1 and 28 to 42 days after dose 1 for Group 2 | |
| Notes: [1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. Justification: Only descriptive data was planned to be reported for this endpoint. | |

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The endpoint was planned to be reported for reporting group 13vPnC Group 1 (Cohort 1) and 13vPnC Group 2 (Cohort 1) only.

| End point values | 13vPnC Group 1 (Cohort 1) | 13vPnC Group 2 (Cohort 1) | | |
|-------------------------------------|---------------------------|---------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 109 | 175 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| Common serotypes - serotype 4 | 98.2 (93.5 to 99.8) | 100 (97.9 to 100) | | |
| Common serotypes - serotype 6B | 100 (96.7 to 100) | 100 (97.9 to 100) | | |
| Common serotypes - serotype 9V | 100 (96.7 to 100) | 100 (97.9 to 100) | | |
| Common serotypes - serotype 14 | 100 (96.7 to 100) | 100 (97.9 to 100) | | |
| Common serotypes - serotype 18C | 100 (96.7 to 100) | 100 (97.9 to 100) | | |
| Common serotypes - serotype 19F | 100 (96.7 to 100) | 100 (97.9 to 100) | | |
| Common serotypes - serotype 23F | 99.1 (95 to 100) | 100 (97.9 to 100) | | |
| Additional serotypes - serotype 1 | 100 (96.7 to 100) | 98.9 (95.9 to 99.9) | | |
| Additional serotypes - serotype 3 | 94.5 (88.4 to 98) | 92 (86.9 to 95.5) | | |
| Additional serotypes - serotype 5 | 100 (96.7 to 100) | 98.9 (95.9 to 99.9) | | |
| Additional serotypes - serotype 6A | 100 (96.7 to 100) | 100 (97.9 to 100) | | |
| Additional serotypes - serotype 7F | 100 (96.7 to 100) | 100 (97.9 to 100) | | |
| Additional serotypes - serotype 19A | 100 (96.7 to 100) | 100 (97.9 to 100) | | |

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Measured 1 Month After Vaccination in Group 3

| | |
|-----------------|---|
| End point title | Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Measured 1 Month After Vaccination in Group 3 ^[3] ^[4] |
|-----------------|---|

End point description:

Antibody GMC for the 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (serotypes 1, 3, 5, 6A, 7F, and 19A) were presented. GMC (13vPnC) and corresponding 2-sided 95% confidence intervals (CI) were evaluated. Geometric means (GMs) were calculated using all subjects with available data for after dose 1 blood draw. EIP: subjects who met all inclusion criteria, received all assigned doses of study vaccine; had at least 1 valid, determinate assay result from blood draw within 27-56 days after last scheduled vaccination for proposed analysis; no major protocol violations.

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

End point timeframe:

28 to 42 days after dose 1 for Group 3

Notes:

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

Justification: Only descriptive data was planned to be reported for this endpoint.

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

Justification: The endpoint was planned to be reported for reporting group 13vPnC Group 3 only.

| End point values | 13vPnC Group 3 | | | |
|--|------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 171 ^[5] | | | |
| Units: mcg/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Common serotypes - serotype 4 | 8.45 (7.24 to 9.87) | | | |
| Common serotypes - serotype 6B | 53.56 (45.48 to 63.07) | | | |
| Common serotypes - serotype 9V | 9.51 (8.38 to 10.78) | | | |
| Common serotypes - serotype 14 | 29.36 (24.78 to 34.78) | | | |
| Common serotypes - serotype 18C | 8.23 (7.13 to 9.51) | | | |
| Common serotypes - serotype 19F | 17.58 (14.95 to 20.67) | | | |
| Common serotypes - serotype 23F | 11.26 (9.79 to 12.95) | | | |
| Additional serotypes - serotype 1 | 3.57 (3.05 to 4.18) | | | |
| Additional serotypes - serotype 3 | 2.38 (2.07 to 2.74) | | | |
| Additional serotypes - serotype 5 | 5.52 (4.82 to 6.32) | | | |
| Additional serotypes - serotype 6A | 21.51 (18.15 to 25.51) | | | |
| Additional serotypes - serotype 7F | 6.24 (5.49 to 7.08) | | | |
| Additional serotypes - serotype 19A | 17.18 (15.01 to 19.67) | | | |

Notes:

[5] - Subjects with determinate antibody concentration.

Statistical analyses

No statistical analyses for this end point

Primary: Serotype-specific Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMTs) 1 Month After Vaccination in Group 3 and 4

| | |
|-----------------|--|
| End point title | Serotype-specific Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMTs) 1 Month After Vaccination in Group 3 and 4 ^[6] |
|-----------------|--|

End point description:

Serotype-specific OPA GMTs for the 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (serotypes 1, 3, 5, 6A, 7F, and 19A) were determined in the blood samples of all the subjects using a microcolony OPA (mcOPA)

assay. GMT (13vPnC) and corresponding 2-sided 95% CI were evaluated. GMs were calculated using all subjects with available data for after dose 1 blood draw. EIP: subjects who met all inclusion criteria, received all assigned doses of study vaccine; had at least 1 valid, determinate assay result from blood draw within 27-56 days after last scheduled vaccination for proposed analysis; no major protocol violations.

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

End point timeframe:

28 to 42 days after dose 1 for Group 3 and 4

Notes:

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

Justification: The endpoint was planned to be reported for reporting group 13vPnC Group 3 and 13vPnC Group 4 only.

| End point values | 13vPnC Group 3 | 13vPnC Group 4 | | |
|--|----------------------------|----------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 189 | 181 | | |
| Units: titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Common serotypes - serotype 4 | 6912 (6101.2 to 7831.4) | 4629 (4017.2 to 5334.3) | | |
| Common serotypes - serotype 6B | 14224 (12316.4 to 16427.3) | 14996 (13164.1 to 17083.1) | | |
| Common serotypes - serotype 9V | 4485 (4001.1 to 5027.5) | 4733 (4203.3 to 5328.4) | | |
| Common serotypes - serotype 14 | 6894 (6028.3 to 7884) | 4759 (4120.4 to 5497) | | |
| Common serotypes - serotype 18C | 6263 (5436.4 to 7215.1) | 8815 (7738.2 to 10041) | | |
| Common serotypes - serotype 19F | 2280 (1949.4 to 2667.6) | 1559 (1293.3 to 1878.9) | | |
| Common serotypes - serotype 23F | 3808 (3354.7 to 4322.6) | 3245 (2818.8 to 3735.5) | | |
| Additional serotypes - serotype 1 | 319 (271.2 to 376) | 187 (160.4 to 218.6) | | |
| Additional serotypes - serotype 3 | 114 (100.4 to 129.4) | 202 (180.9 to 226.3) | | |
| Additional serotypes - serotype 5 | 336 (270.3 to 417.6) | 491 (426.3 to 565.3) | | |
| Additional serotypes - serotype 6A | 9928 (8457 to 11654.8) | 7514 (6350.8 to 8890.7) | | |
| Additional serotypes - serotype 7F | 6584 (5829.4 to 7435.5) | 10334 (9099 to 11736.8) | | |
| Additional serotypes - serotype 19A | 1276 (1131.7 to 1439) | 1180 (1047.5 to 1329.4) | | |

Statistical analyses

| | |
|----------------------------|------------|
| Statistical analysis title | Serotype 4 |
|----------------------------|------------|

Statistical analysis description:

CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC Group 4 – 13vPnC Group 3).

| | |
|-------------------|---------------------------------|
| Comparison groups | 13vPnC Group 4 v 13vPnC Group 3 |
|-------------------|---------------------------------|

| | |
|---|--------------------------------|
| Number of subjects included in analysis | 370 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[7] |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.24 |
| upper limit | 1.8 |

Notes:

[7] - Non-inferiority was to be concluded if the lower bound of the 2-sided 95% CI was greater than 0.5.

| | |
|-----------------------------------|-------------|
| Statistical analysis title | Serotype 6B |
|-----------------------------------|-------------|

Statistical analysis description:

CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC Group 4 – 13vPnC Group 3).

| | |
|---|---------------------------------|
| Comparison groups | 13vPnC Group 3 v 13vPnC Group 4 |
| Number of subjects included in analysis | 370 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[8] |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.78 |
| upper limit | 1.15 |

Notes:

[8] - Non-inferiority was to be concluded if the lower bound of the 2-sided 95% CI was greater than 0.5.

| | |
|-----------------------------------|-------------|
| Statistical analysis title | Serotype 9V |
|-----------------------------------|-------------|

Statistical analysis description:

CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC Group 4 – 13vPnC Group 3).

| | |
|---|---------------------------------|
| Comparison groups | 13vPnC Group 4 v 13vPnC Group 3 |
| Number of subjects included in analysis | 370 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[9] |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.8 |
| upper limit | 1.12 |

Notes:

[9] - Non-inferiority was to be concluded if the lower bound of the 2-sided 95% CI was greater than 0.5.

| | |
|-----------------------------------|-------------|
| Statistical analysis title | Serotype 14 |
|-----------------------------------|-------------|

Statistical analysis description:

CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC Group 4 – 13vPnC Group 3).

| | |
|---|---------------------------------|
| Comparison groups | 13vPnC Group 4 v 13vPnC Group 3 |
| Number of subjects included in analysis | 370 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[10] |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.19 |
| upper limit | 1.76 |

Notes:

[10] - Non-inferiority was to be concluded if the lower bound of the 2-sided 95% CI was greater than 0.5.

| | |
|-----------------------------------|--------------|
| Statistical analysis title | Serotype 18C |
|-----------------------------------|--------------|

Statistical analysis description:

CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC Group 4 – 13vPnC Group 3).

| | |
|---|---------------------------------|
| Comparison groups | 13vPnC Group 4 v 13vPnC Group 3 |
| Number of subjects included in analysis | 370 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[11] |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.59 |
| upper limit | 0.86 |

Notes:

[11] - Non-inferiority was to be concluded if the lower bound of the 2-sided 95% CI was greater than 0.5.

| | |
|-----------------------------------|--------------|
| Statistical analysis title | Serotype 19F |
|-----------------------------------|--------------|

Statistical analysis description:

CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC Group 4 – 13vPnC Group 3).

| | |
|---|---------------------------------|
| Comparison groups | 13vPnC Group 4 v 13vPnC Group 3 |
| Number of subjects included in analysis | 370 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[12] |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.5 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.15 |
| upper limit | 1.86 |

Notes:

[12] - Non-inferiority was to be concluded if the lower bound of the 2-sided 95% CI was greater than 0.5.

| | |
|-----------------------------------|--------------|
| Statistical analysis title | Serotype 23F |
|-----------------------------------|--------------|

Statistical analysis description:

CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC Group 4 – 13vPnC Group 3).

| | |
|---|---------------------------------|
| Comparison groups | 13vPnC Group 4 v 13vPnC Group 3 |
| Number of subjects included in analysis | 370 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[13] |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.2 |

Confidence interval

| | |
|-------------|---------|
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.97 |
| upper limit | 1.42 |

Notes:

[13] - Non-inferiority was to be concluded if the lower bound of the 2-sided 95% CI was greater than 0.5.

| | |
|-----------------------------------|------------|
| Statistical analysis title | Serotype 1 |
|-----------------------------------|------------|

Statistical analysis description:

CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC Group 4 – 13vPnC Group 3).

| | |
|---|---------------------------------|
| Comparison groups | 13vPnC Group 4 v 13vPnC Group 3 |
| Number of subjects included in analysis | 370 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[14] |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.7 |

Confidence interval

| | |
|-------------|---------|
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.36 |
| upper limit | 2.13 |

Notes:

[14] - Non-inferiority was to be concluded if the lower bound of the 2-sided 95% CI was greater than 0.5.

| | |
|-----------------------------------|------------|
| Statistical analysis title | Serotype 3 |
|-----------------------------------|------------|

Statistical analysis description:

CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC Group 4 – 13vPnC Group 3).

| | |
|---|---------------------------------|
| Comparison groups | 13vPnC Group 4 v 13vPnC Group 3 |
| Number of subjects included in analysis | 370 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[15] |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.48 |
| upper limit | 0.67 |

Notes:

[15] - Non-inferiority was to be concluded if the lower bound of the 2-sided 95% CI was greater than 0.5.

| | |
|-----------------------------------|------------|
| Statistical analysis title | Serotype 5 |
|-----------------------------------|------------|

Statistical analysis description:

CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC Group 4 – 13vPnC Group 3).

| | |
|---|---------------------------------|
| Comparison groups | 13vPnC Group 4 v 13vPnC Group 3 |
| Number of subjects included in analysis | 370 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[16] |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.53 |
| upper limit | 0.89 |

Notes:

[16] - Non-inferiority was to be concluded if the lower bound of the 2-sided 95% CI was greater than 0.5.

| | |
|-----------------------------------|-------------|
| Statistical analysis title | Serotype 6A |
|-----------------------------------|-------------|

Statistical analysis description:

CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC Group 4 – 13vPnC Group 3).

| | |
|---|---------------------------------|
| Comparison groups | 13vPnC Group 4 v 13vPnC Group 3 |
| Number of subjects included in analysis | 370 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[17] |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.05 |
| upper limit | 1.67 |

Notes:

[17] - Non-inferiority was to be concluded if the lower bound of the 2-sided 95% CI was greater than 0.5.

| | |
|-----------------------------------|-------------|
| Statistical analysis title | Serotype 7F |
|-----------------------------------|-------------|

Statistical analysis description:

CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC Group 4 – 13vPnC Group 3).

| | |
|---|---------------------------------|
| Comparison groups | 13vPnC Group 4 v 13vPnC Group 3 |
| Number of subjects included in analysis | 370 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[18] |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.53 |
| upper limit | 0.76 |

Notes:

[18] - Non-inferiority was to be concluded if the lower bound of the 2-sided 95% CI was greater than 0.5.

| | |
|-----------------------------------|--------------|
| Statistical analysis title | Serotype 19A |
|-----------------------------------|--------------|

Statistical analysis description:

CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC Group 4 – 13vPnC Group 3).

| | |
|---|---------------------------------|
| Comparison groups | 13vPnC Group 4 v 13vPnC Group 3 |
| Number of subjects included in analysis | 370 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[19] |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.91 |
| upper limit | 1.28 |

Notes:

[19] - Non-inferiority was to be concluded if the lower bound of the 2-sided 95% CI was greater than 0.5.

Primary: Comparison of Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Measured 1 Month After 13vPnC Vaccination in Group 3 Relative to Posttoddler Responses in Study 6096A1-3005 (NCT00444457)

| | |
|-----------------|---|
| End point title | Comparison of Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Measured 1 Month After 13vPnC Vaccination in Group 3 Relative to Posttoddler Responses in Study 6096A1-3005 (NCT00444457) ^{[20][21]} |
|-----------------|---|

End point description:

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

End point timeframe:

28 to 42 days after dose 1

Notes:

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

Justification: Only descriptive data was planned to be reported for this endpoint.

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

Justification: The endpoint was planned to be reported for reporting group 13vPnC Group 3 only.

| | | | | |
|--------------------------------------|-------------------|--|--|--|
| End point values | 13vPnC Group 3 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 0 ^[22] | | | |
| Units: mcg/mL | | | | |
| arithmetic mean (standard deviation) | () | | | |

Notes:

[22] - Data not reported because analysis population includes subjects who were not enrolled in this study.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Prespecified Local Reactions Within 7 Days of Dose 1

| | |
|-----------------|---|
| End point title | Percentage of Subjects Reporting Prespecified Local Reactions Within 7 Days of Dose 1 |
|-----------------|---|

End point description:

Local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant (present and interfered with limb movement). Redness and swelling were scaled as Any (redness or swelling present); Mild (0.5 centimeters [cm] to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (> 7.0 cm). Dose 1 Safety Population: all subjects who received the first dose of 13vPnC.'n'=number of subjects with known values for specified local reaction for each group respectively. Subjects may be represented in more than 1 category.

| | |
|----------------|---------------------|
| End point type | Other pre-specified |
|----------------|---------------------|

End point timeframe:

From the day of dose 1 (Day 1) to Day 7 after dose 1

| | | | | |
|--|---------------------------|---------------------------|---------------------------|---------------------------|
| End point values | 13vPnC Group 1 (Cohort 1) | 13vPnC Group 2 (Cohort 1) | 13vPnC Group 1 (Cohort 2) | 13vPnC Group 2 (Cohort 2) |
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 110 ^[23] | 158 ^[24] | 151 ^[25] | 102 ^[26] |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Tenderness Any (n=108,155,148,102,265,283) | 50.9 | 61.9 | 45.3 | 62.7 |
| Tenderness Significant (n=92,141,133,92,221,242) | 7.6 | 10.6 | 5.3 | 13 |
| Swelling Any (n=97,144,142,90,226,233) | 25.8 | 22.2 | 17.6 | 20 |
| Swelling Mild (n=94,143,141,89,220,221) | 21.3 | 20.3 | 14.2 | 13.5 |

| | | | | |
|--|------|------|------|------|
| Swelling Moderate (n=94,141,135,89,219,226) | 9.6 | 5.7 | 7.4 | 11.2 |
| Swelling Severe (n=90,138,131,88,211,214) | 0 | 0 | 0 | 1.1 |
| Redness Any (n=103,149,143,91,233,232) | 39.8 | 34.9 | 18.9 | 36.3 |
| Redness Mild (n=99,146,143,90,226,226) | 31.3 | 31.5 | 16.8 | 31.1 |
| Redness Moderate (n=94,142,135,89,218,221) | 12.8 | 9.9 | 5.9 | 14.6 |
| Redness Severe (n=90,138,131,88,212,213) | 0 | 0 | 0.8 | 1.1 |

Notes:

[23] - Subjects with known values for any local reaction.

[24] - Subjects with known values for any local reaction.

[25] - Subjects with known values for any local reaction.

[26] - Subjects with known values for any local reaction.

| End point values | 13vPnC Group 3 | 13vPnC Group 4 | | |
|---|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 270 ^[27] | 285 ^[28] | | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Tenderness Any (n=108,155, 148,102,265,283) | 86.8 | 89 | | |
| Tenderness Significant (n=92,141,133,92,221,242) | 19.5 | 43.8 | | |
| Swelling Any (n=97,144,142,90,226,233) | 37.6 | 36.9 | | |
| Swelling Mild (n=94,143,141,89,220,221) | 21.8 | 22.6 | | |
| Swelling Moderate (n=94,141,135,89,219,226) | 21.9 | 21.2 | | |
| Swelling Severe (n=90,138,131,88,211,214) | 3.3 | 1.9 | | |
| Redness Any (n=103,149,143,91,233,232) | 42.9 | 30.2 | | |
| Redness Mild (n=99,146,143,90,226,226) | 27.9 | 21.2 | | |
| Redness Moderate (n=94,142,135,89,218,221) | 22 | 14 | | |
| Redness Severe (n=90,138,131,88,212,213) | 3.3 | 1.9 | | |

Notes:

[27] - Subjects with known values for any local reaction.

[28] - Subjects with known values for any local reaction.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Prespecified Local Reactions Within 7 Days of Dose 2

| | |
|-----------------|---|
| End point title | Percentage of Subjects Reporting Prespecified Local Reactions Within 7 Days of Dose 2 ^[29] |
|-----------------|---|

End point description:

Local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness

present); Significant (present and interfered with limb movement). Redness and swelling were scaled as Any (redness or swelling present); Mild (0.5 centimeters [cm] to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (> 7.0 cm). Dose 2 Safety Population: all subjects who received 2 doses of 13vPnC. Here, 'n'=number of subjects with known values for specified local reaction for each group respectively. Subjects may be represented in more than 1 category.

| | |
|----------------|---------------------|
| End point type | Other pre-specified |
|----------------|---------------------|

End point timeframe:

From the day of dose 2 (Day 1) to Day 7 of dose 2

Notes:

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

Justification: The endpoint was planned to be reported for reporting group 13vPnC Group 1 (Cohort 1) and 13vPnC Group 2 (Cohort 1) only.

| End point values | 13vPnC Group 1 (Cohort 1) | 13vPnC Group 1 (Cohort 2) | | |
|------------------------------------|---------------------------|---------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 90 ^[30] | 131 ^[31] | | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Tenderness Any (n=87, 125) | 57.5 | 55.2 | | |
| Tenderness Significant (n=68, 101) | 8.8 | 9.9 | | |
| Swelling Any (n=73, 105) | 23.3 | 17.1 | | |
| Swelling Mild (n=72, 104) | 22.2 | 15.4 | | |
| Swelling Moderate (n=69, 102) | 2.9 | 7.8 | | |
| Swelling Severe (n=68, 98) | 0 | 0 | | |
| Redness Any (n=76, 110) | 35.5 | 23.6 | | |
| Redness Mild (n=74, 108) | 33.8 | 18.5 | | |
| Redness Moderate (n=70, 100) | 7.1 | 6 | | |
| Redness Severe (n=68, 98) | 0 | 0 | | |

Notes:

[30] - Subjects with known values for any local reaction.

[31] - Subjects with known values for any local reaction.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Prespecified Systemic Events Within 7 Days of Dose 1

| | |
|-----------------|---|
| End point title | Percentage of Subjects Reporting Prespecified Systemic Events Within 7 Days of Dose 1 |
|-----------------|---|

End point description:

Systemic events (any fever ≥ 38 degrees [deg] Celsius [C], decreased appetite, irritability, increased sleep, decreased sleep, and hives [urticaria]) were reported using an electronic diary. Dose 1 Safety Population: all subjects who received the first dose of 13vPnC. Here, 'n'=number of subjects with known values for specified systemic events for each group respectively. Subjects may be represented in more than 1 category.

| | |
|----------------|---------------------|
| End point type | Other pre-specified |
|----------------|---------------------|

End point timeframe:

From the day of dose 1 (Day 1) to Day 7 of dose 1

| End point values | 13vPnC Group 1 (Cohort 1) | 13vPnC Group 2 (Cohort 1) | 13vPnC Group 1 (Cohort 2) | 13vPnC Group 2 (Cohort 2) |
|---|---------------------------|---------------------------|---------------------------|---------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 112 ^[32] | 157 ^[33] | 165 ^[34] | 107 ^[35] |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Fever ≥ 38 to ≤ 39 degC (n=92,138,137,90,212,214) | 16.3 | 5.1 | 17.5 | 14.4 |
| Fever > 39 but ≤ 40 degC (n=90,138,130,89,212,212) | 4.4 | 0.7 | 4.6 | 3.4 |
| Fever > 40 degC (n=90,138,130,88,210,212) | 0 | 0.7 | 0 | 1.1 |
| Decreased appetite (n=99,149,146,94,227,223) | 42.4 | 24.8 | 39.7 | 34 |
| Irritability (n=108,151,156,102,234,234) | 60.2 | 39.7 | 72.4 | 52 |
| Increased sleep (n=98,145,146,97,226,229) | 32.7 | 15.9 | 37 | 23.7 |
| Decreased sleep (n=97,143,140,91,212,224) | 22.7 | 14 | 32.1 | 18.7 |
| Hives (urticaria) (n=90,139,131,88,213,214) | 1.1 | 0.7 | 1.5 | 4.5 |

Notes:

[32] - Subjects with known values for any systemic events.

[33] - Subjects with known values for any systemic events.

[34] - Subjects with known values for any systemic events.

[35] - Subjects with known values for any systemic events.

| End point values | 13vPnC Group 3 | 13vPnC Group 4 | | |
|---|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 250 ^[36] | 253 ^[37] | | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Fever ≥ 38 to ≤ 39 degC (n=92,138,137,90,212,214) | 4.2 | 5.1 | | |
| Fever > 39 but ≤ 40 degC (n=90,138,130,89,212,212) | 2.4 | 0.5 | | |
| Fever > 40 degC (n=90,138,130,88,210,212) | 0.5 | 0.5 | | |
| Decreased appetite (n=99,149,146,94,227,223) | 22.9 | 22.9 | | |
| Irritability (n=108,151,156,102,234,234) | 31.2 | 25.2 | | |
| Increased sleep (n=98,145,146,97,226,229) | 21.2 | 26.6 | | |
| Decreased sleep (n=97,143,140,91,212,224) | 5.7 | 18.8 | | |
| Hives (urticaria) (n=90,139,131,88,213,214) | 1.9 | 1.4 | | |

Notes:

[36] - Subjects with known values for any systemic events.

[37] - Subjects with known values for any systemic events.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Prespecified Systemic Events Within 7 Days of Dose 2

| | |
|-----------------|---|
| End point title | Percentage of Subjects Reporting Prespecified Systemic Events Within 7 Days of Dose 2 ^[38] |
|-----------------|---|

End point description:

Systemic events (any fever ≥ 38 deg C, decreased appetite, irritability, increased sleep, decreased sleep, and hives [urticaria]) were reported using an electronic diary. Subjects may have been represented in more than 1 category. Percentage of subjects = number of subjects reporting specified systemic event divided by number of subjects reporting yes for at least 1 day or no for all days. Dose 2 Safety Population: all subjects who received 2 doses of 13vPnC. Here, 'n'=number of subjects with known values for specified systemic events for each group respectively. Subjects may be represented in more than 1 category.

| | |
|----------------|---------------------|
| End point type | Other pre-specified |
|----------------|---------------------|

End point timeframe:

From the day of dose 2 (Day 1) to Day 7 of dose 2

Notes:

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

Justification: The endpoint was planned to be reported for reporting group 13vPnC Group 1 (Cohort 1) and 13vPnC Group 1 (Cohort 2) only.

| End point values | 13vPnC Group 1 (Cohort 1) | 13vPnC Group 1 (Cohort 2) | | |
|---|---------------------------|---------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 91 ^[39] | 137 ^[40] | | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Fever ≥ 38 but ≤ 39 degC (n=70,101) | 14.3 | 11.9 | | |
| Fever > 39 but ≤ 40 degC (n=68, 100) | 4.4 | 2 | | |
| Fever > 40 degC (n=68, 98) | 0 | 1 | | |
| Decreased appetite (n=77, 113) | 40.3 | 34.5 | | |
| Irritability (n=86, 126) | 65.1 | 61.1 | | |
| Increased sleep (n=75, 109) | 29.3 | 23.9 | | |
| Decreased sleep (n=77, 112) | 28.6 | 26.8 | | |
| Hives (urticaria) (n=68, 98) | 2.9 | 0 | | |

Notes:

[39] - Subjects with known values for any systemic events.

[40] - Subjects with known values for any systemic events.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Group 1: Baseline up to Day 280; Group 2, 3 and 4: Baseline up to Day 210. Participants recorded pre-specified AEs in electronic diary: local reactions; systemic events (up to 7 days after each vaccine dose)

Adverse event reporting additional description:

SAEs and AEs were grouped by system organ class and summarized. AEs included solicited AEs collected in the electronic diary (local and systemic reactions; systematic assessment) and unsolicited events collected on the case report form at each visit (nonsystematic assessment). Version was not captured, hence 0.0 is mentioned for dictionary version.

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

Dictionary used

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

| | |
|--------------------|-----|
| Dictionary version | 0.0 |
|--------------------|-----|

Reporting groups

| | |
|-----------------------|----------------------------------|
| Reporting group title | 13vPnC Group 1 (Cohort 1) Dose 1 |
|-----------------------|----------------------------------|

Reporting group description:

13vPnC (0.5mL dose) administered intramuscularly at baseline. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled prior to protocol amendment to increase sample size (Cohort 1).

| | |
|-----------------------|----------------------------------|
| Reporting group title | 13vPnC Group 1 (Cohort 1) Dose 2 |
|-----------------------|----------------------------------|

Reporting group description:

13vPnC (0.5mL dose) administered intramuscularly anytime from Day 56 to Day 70. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled prior to protocol amendment to increase sample size (Cohort 1).

| | |
|-----------------------|----------------------------------|
| Reporting group title | 13vPnC Group 2 (Cohort 1) Dose 1 |
|-----------------------|----------------------------------|

Reporting group description:

13vPnC (0.5mL dose) administered intramuscularly at baseline. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled prior to protocol amendment to increase sample size (Cohort 1).

| | |
|-----------------------|----------------------------------|
| Reporting group title | 13vPnC Group 1 (Cohort 2) Dose 1 |
|-----------------------|----------------------------------|

Reporting group description:

13vPnC (0.5mL dose) administered intramuscularly at baseline. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled after protocol amendment to increase sample size (Cohort 2).

| | |
|-----------------------|----------------------------------|
| Reporting group title | 13vPnC Group 1 (Cohort 2) Dose 2 |
|-----------------------|----------------------------------|

Reporting group description:

13vPnC (0.5mL dose) administered intramuscularly anytime from Day 56 to Day 70. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled after protocol amendment to increase sample size (Cohort 2).

| | |
|-----------------------|----------------------------------|
| Reporting group title | 13vPnC Group 2 (Cohort 2) Dose 1 |
|-----------------------|----------------------------------|

Reporting group description:

13vPnC (0.5mL dose) administered intramuscularly at baseline. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled after protocol amendment to increase sample size (Cohort 2).

| | |
|-----------------------|---|
| Reporting group title | 6-Month Follow-up 13vPnC Group 1 (Cohort 1 and 2) |
|-----------------------|---|

Reporting group description:

6-month follow-up telephone contact for subjects in Group 1 (Cohort 1 and 2).

| | |
|-----------------------|---|
| Reporting group title | 6-Month Follow-up 13vPnC Group 2 (Cohort 1 and 2) |
|-----------------------|---|

Reporting group description:

6-month follow-up telephone contact for subjects in Group 2 (Cohort 1 and 2).

| | |
|-----------------------|----------------|
| Reporting group title | 13vPnC Group 3 |
|-----------------------|----------------|

Reporting group description:

13vPnC (0.5mL dose) administered intramuscularly at baseline. Subjects must have previously received

at least 1 dose of 7vPnC.

| | |
|--|----------------------------------|
| Reporting group title | 6-Month Follow-up 13vPnC Group 3 |
| Reporting group description: 6-month follow-up telephone contact for subjects in Group 3. | |
| Reporting group title | 13vPnC Group 4 |
| Reporting group description: 13vPnC (0.5mL dose) administered intramuscularly at baseline. Subjects must not have received 7vPnC or any other pneumococcal vaccine. | |
| Reporting group title | 6-Month Follow-up 13vPnC Group 4 |
| Reporting group description: 6 -Month Follow-up Telephone Contact for subjects in Group 4. | |

| Serious adverse events | 13vPnC Group 1 (Cohort 1) Dose 1 | 13vPnC Group 1 (Cohort 1) Dose 2 | 13vPnC Group 2 (Cohort 1) Dose 1 |
|---|-------------------------------------|-------------------------------------|-------------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 2 / 112 (1.79%) | 1 / 179 (0.56%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Near drowning | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (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 injury | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Febrile convulsion | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (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 | | | |
| Vomiting | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (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 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| Wheezing | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 1 / 179 (0.56%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (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 asthmaticus | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (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 | | | |
| Nephrotic syndrome | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (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 | | | |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 1 / 179 (0.56%) |
| 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 / 124 (0.00%) | 1 / 112 (0.89%) | 0 / 179 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus bronchiolitis | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 1 / 112 (0.89%) | 0 / 179 (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 | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (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 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Staphylococcal infection | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (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 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (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 | 13vPnC Group 1 (Cohort 2) Dose 1 | 13vPnC Group 1 (Cohort 2) Dose 2 | 13vPnC Group 2 (Cohort 2) Dose 1 |
|---|-------------------------------------|-------------------------------------|-------------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 175 (0.57%) | 4 / 165 (2.42%) | 0 / 118 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Near drowning | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 1 / 165 (0.61%) | 0 / 118 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal injury | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Febrile convulsion | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (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 | | | |
| Vomiting | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (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 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| Wheezing | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (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 / 175 (0.57%) | 0 / 165 (0.00%) | 0 / 118 (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 |
| Status asthmaticus | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (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 | | | |
| Nephrotic syndrome | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (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 | | | |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (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 |
| Gastroenteritis rotavirus | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 1 / 165 (0.61%) | 0 / 118 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus bronchiolitis | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (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 | 0 / 175 (0.00%) | 1 / 165 (0.61%) | 0 / 118 (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 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Staphylococcal infection | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 1 / 165 (0.61%) | 0 / 118 (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 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (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 | 6-Month Follow-up 13vPnC Group 1 (Cohort 1 and 2) | 6-Month Follow-up 13vPnC Group 2 (Cohort 1 and 2) | 13vPnC Group 3 |
|---|---|---|-----------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 3 / 299 (1.00%) | 1 / 297 (0.34%) | 1 / 294 (0.34%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Near drowning | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (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 injury | | | |
| subjects affected / exposed | 1 / 299 (0.33%) | 0 / 297 (0.00%) | 0 / 294 (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 |
| Nervous system disorders | | | |
| Febrile convulsion | | | |
| subjects affected / exposed | 1 / 299 (0.33%) | 0 / 297 (0.00%) | 0 / 294 (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 |
| Gastrointestinal disorders | | | |
| Vomiting | | | |
| subjects affected / exposed | 1 / 299 (0.33%) | 0 / 297 (0.00%) | 0 / 294 (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, thoracic and mediastinal disorders | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| Wheezing | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (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 | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (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 asthmaticus | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 1 / 297 (0.34%) | 0 / 294 (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 |
| Renal and urinary disorders | | | |
| Nephrotic syndrome | | | |
| subjects affected / exposed | 1 / 299 (0.33%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (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 |
| Gastroenteritis rotavirus | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (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 | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (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 | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (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 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Staphylococcal infection | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (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 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 1 / 294 (0.34%) |
| 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 | 6-Month Follow-up 13vPnC Group 3 | 13vPnC Group 4 | 6-Month Follow-up 13vPnC Group 4 |
|---|-------------------------------------|-----------------|-------------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 1 / 298 (0.34%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Near drowning | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (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 injury | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Febrile convulsion | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (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 | | | |
| Vomiting | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (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 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| Wheezing | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (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 | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 1 / 298 (0.34%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Status asthmaticus | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (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 | | | |
| Nephrotic syndrome | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (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 | | | |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (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 |
| Gastroenteritis rotavirus | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (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 | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (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 | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (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 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Staphylococcal infection | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (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 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (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 |

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

| Non-serious adverse events | 13vPnC Group 1 (Cohort 1) Dose 1 | 13vPnC Group 1 (Cohort 1) Dose 2 | 13vPnC Group 2 (Cohort 1) Dose 1 |
|---|-------------------------------------|-------------------------------------|-------------------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 88 / 124 (70.97%) | 71 / 112 (63.39%) | 112 / 179 (62.57%) |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 5 / 124 (4.03%) | 3 / 112 (2.68%) | 3 / 179 (1.68%) |
| occurrences (all) | 5 | 3 | 3 |
| Injection site pruritus | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 1 / 179 (0.56%) |
| occurrences (all) | 0 | 0 | 1 |
| Influenza like illness | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site reaction | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site pain | | | |

| | | | |
|---|--|------------------|-------------------|
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fever >=38 degrees C but <=39 degrees C | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[1] | 15 / 92 (16.30%) | 10 / 70 (14.29%) | 7 / 138 (5.07%) |
| occurrences (all) | 15 | 10 | 7 |
| Fever >39 degrees C but <=40 degrees C | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[2] | 4 / 90 (4.44%) | 3 / 68 (4.41%) | 1 / 138 (0.72%) |
| occurrences (all) | 4 | 3 | 1 |
| Fever >40 degrees C | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[3] | 0 / 90 (0.00%) | 0 / 68 (0.00%) | 1 / 138 (0.72%) |
| occurrences (all) | 0 | 0 | 1 |
| Decreased appetite | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[4] | 42 / 99 (42.42%) | 31 / 77 (40.26%) | 37 / 149 (24.83%) |
| occurrences (all) | 42 | 31 | 37 |
| Irritability | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[5] | 65 / 108 (60.19%) | 56 / 86 (65.12%) | 60 / 151 (39.74%) |
| occurrences (all) | 65 | 56 | 60 |
| Increased sleep | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |

| | | | |
|--|---|-----------------------------------|------------------------------------|
| <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[6]</p> <p>occurrences (all)</p> | <p>32 / 98 (32.65%)</p> <p>32</p> | <p>22 / 75 (29.33%)</p> <p>22</p> | <p>23 / 145 (15.86%)</p> <p>23</p> |
| <p>Decreased sleep</p> | <p>Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.</p> | | |
| <p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[7]</p> <p>occurrences (all)</p> | <p>22 / 97 (22.68%)</p> <p>22</p> | <p>22 / 77 (28.57%)</p> <p>22</p> | <p>20 / 143 (13.99%)</p> <p>20</p> |
| <p>Hives (urticaria)</p> | <p>Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.</p> | | |
| <p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[8]</p> <p>occurrences (all)</p> | <p>1 / 90 (1.11%)</p> <p>1</p> | <p>2 / 68 (2.94%)</p> <p>2</p> | <p>1 / 139 (0.72%)</p> <p>1</p> |
| <p>Immune system disorders</p> <p>Drug hypersensitivity</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 124 (0.00%)</p> <p>0</p> | <p>0 / 112 (0.00%)</p> <p>0</p> | <p>0 / 179 (0.00%)</p> <p>0</p> |
| <p>Seasonal allergy</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 124 (0.00%)</p> <p>0</p> | <p>0 / 112 (0.00%)</p> <p>0</p> | <p>0 / 179 (0.00%)</p> <p>0</p> |
| <p>Reproductive system and breast disorders</p> <p>Vulvovaginal discomfort</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 124 (0.00%)</p> <p>0</p> | <p>0 / 112 (0.00%)</p> <p>0</p> | <p>0 / 179 (0.00%)</p> <p>0</p> |
| <p>Penile adhesion</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 124 (0.00%)</p> <p>0</p> | <p>0 / 112 (0.00%)</p> <p>0</p> | <p>0 / 179 (0.00%)</p> <p>0</p> |
| <p>Respiratory, thoracic and mediastinal disorders</p> <p>Cough</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>5 / 124 (4.03%)</p> <p>5</p> | <p>0 / 112 (0.00%)</p> <p>0</p> | <p>7 / 179 (3.91%)</p> <p>7</p> |
| <p>Rhinorrhoea</p> | | | |

| | | | |
|--------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 5 / 124 (4.03%) | 2 / 112 (1.79%) | 4 / 179 (2.23%) |
| occurrences (all) | 6 | 2 | 4 |
| Epistaxis | | | |
| subjects affected / exposed | 2 / 124 (1.61%) | 0 / 112 (0.00%) | 1 / 179 (0.56%) |
| occurrences (all) | 2 | 0 | 1 |
| Nasal congestion | | | |
| subjects affected / exposed | 1 / 124 (0.81%) | 1 / 112 (0.89%) | 1 / 179 (0.56%) |
| occurrences (all) | 1 | 1 | 1 |
| Pneumonitis | | | |
| subjects affected / exposed | 1 / 124 (0.81%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Sinus congestion | | | |
| subjects affected / exposed | 1 / 124 (0.81%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Wheezing | | | |
| subjects affected / exposed | 1 / 124 (0.81%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 4 / 179 (2.23%) |
| occurrences (all) | 0 | 0 | 4 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 1 / 179 (0.56%) |
| occurrences (all) | 0 | 0 | 1 |
| Rhinitis allergic | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 1 / 179 (0.56%) |
| occurrences (all) | 0 | 0 | 1 |
| Bronchospasm | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Interstitial lung disease | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paranasal sinus hypersecretion | | | |

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|---|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 124 (0.00%) 0 | 0 / 112 (0.00%) 0 | 0 / 179 (0.00%) 0 |
| Sneezing subjects affected / exposed occurrences (all) | 0 / 124 (0.00%) 0 | 0 / 112 (0.00%) 0 | 0 / 179 (0.00%) 0 |
| Psychiatric disorders | | | |
| Breath holding subjects affected / exposed occurrences (all) | 0 / 124 (0.00%) 0 | 0 / 112 (0.00%) 0 | 0 / 179 (0.00%) 0 |
| Sleep disorder subjects affected / exposed occurrences (all) | 0 / 124 (0.00%) 0 | 0 / 112 (0.00%) 0 | 0 / 179 (0.00%) 0 |
| Asperger's disorder subjects affected / exposed occurrences (all) | 0 / 124 (0.00%) 0 | 0 / 112 (0.00%) 0 | 0 / 179 (0.00%) 0 |
| Attention deficit/hyperactivity disorder subjects affected / exposed occurrences (all) | 0 / 124 (0.00%) 0 | 0 / 112 (0.00%) 0 | 0 / 179 (0.00%) 0 |
| Anxiety subjects affected / exposed occurrences (all) | 0 / 124 (0.00%) 0 | 0 / 112 (0.00%) 0 | 0 / 179 (0.00%) 0 |
| Depression subjects affected / exposed occurrences (all) | 0 / 124 (0.00%) 0 | 0 / 112 (0.00%) 0 | 0 / 179 (0.00%) 0 |
| Investigations | | | |
| Cardiac murmur subjects affected / exposed occurrences (all) | 0 / 124 (0.00%) 0 | 0 / 112 (0.00%) 0 | 0 / 179 (0.00%) 0 |
| Heart rate decreased subjects affected / exposed occurrences (all) | 0 / 124 (0.00%) 0 | 0 / 112 (0.00%) 0 | 0 / 179 (0.00%) 0 |
| Injury, poisoning and procedural complications | | | |
| Skin laceration subjects affected / exposed occurrences (all) | 1 / 124 (0.81%) 1 | 0 / 112 (0.00%) 0 | 0 / 179 (0.00%) 0 |
| Excoriation | | | |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 1 / 179 (0.56%) |
| occurrences (all) | 0 | 0 | 1 |
| Lower limb fracture | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 1 / 179 (0.56%) |
| occurrences (all) | 0 | 0 | 1 |
| Head injury | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Laceration | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mouth injury | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Burns second degree | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Traumatic brain injury | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ulna fracture | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye injury | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand fracture | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periorbital haematoma | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthropod bite | | | |

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| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Foot fracture | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Limb injury | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle strain | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wrist fracture | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 1 / 124 (0.81%) | 0 / 112 (0.00%) | 1 / 179 (0.56%) |
| occurrences (all) | 1 | 0 | 1 |
| Speech disorder developmental | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Presyncope | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dizziness | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Migraine | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

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| Somnolence subjects affected / exposed occurrences (all) | 0 / 124 (0.00%) 0 | 0 / 112 (0.00%) 0 | 0 / 179 (0.00%) 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia subjects affected / exposed occurrences (all) | 0 / 124 (0.00%) 0 | 0 / 112 (0.00%) 0 | 0 / 179 (0.00%) 0 |
| Leukocytosis subjects affected / exposed occurrences (all) | 0 / 124 (0.00%) 0 | 0 / 112 (0.00%) 0 | 0 / 179 (0.00%) 0 |
| Ear and labyrinth disorders | | | |
| Ear pain subjects affected / exposed occurrences (all) | 0 / 124 (0.00%) 0 | 0 / 112 (0.00%) 0 | 1 / 179 (0.56%) 1 |
| Eustachian tube dysfunction subjects affected / exposed occurrences (all) | 0 / 124 (0.00%) 0 | 0 / 112 (0.00%) 0 | 0 / 179 (0.00%) 0 |
| Eye disorders | | | |
| Conjunctivitis subjects affected / exposed occurrences (all) | 2 / 124 (1.61%) 2 | 4 / 112 (3.57%) 4 | 2 / 179 (1.12%) 2 |
| Hypermetropia subjects affected / exposed occurrences (all) | 0 / 124 (0.00%) 0 | 0 / 112 (0.00%) 0 | 0 / 179 (0.00%) 0 |
| Eye swelling subjects affected / exposed occurrences (all) | 0 / 124 (0.00%) 0 | 0 / 112 (0.00%) 0 | 0 / 179 (0.00%) 0 |
| Lacrimation increased subjects affected / exposed occurrences (all) | 0 / 124 (0.00%) 0 | 0 / 112 (0.00%) 0 | 0 / 179 (0.00%) 0 |
| Myopia subjects affected / exposed occurrences (all) | 0 / 124 (0.00%) 0 | 0 / 112 (0.00%) 0 | 0 / 179 (0.00%) 0 |
| Gastrointestinal disorders | | | |
| Vomiting subjects affected / exposed occurrences (all) | 7 / 124 (5.65%) 7 | 1 / 112 (0.89%) 1 | 1 / 179 (0.56%) 1 |

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| Diarrhoea | | | |
| subjects affected / exposed | 6 / 124 (4.84%) | 1 / 112 (0.89%) | 4 / 179 (2.23%) |
| occurrences (all) | 6 | 1 | 4 |
| Constipation | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 1 / 112 (0.89%) | 1 / 179 (0.56%) |
| occurrences (all) | 0 | 1 | 1 |
| Tongue coated | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 1 / 112 (0.89%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Duodenogastric reflux | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip dry | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Teething | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritable bowel syndrome | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Toothache | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Uvulitis | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

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| Skin and subcutaneous tissue disorders | | | |
| Rash | | | |
| subjects affected / exposed | 2 / 124 (1.61%) | 2 / 112 (1.79%) | 2 / 179 (1.12%) |
| occurrences (all) | 2 | 2 | 2 |
| Dermatitis | | | |
| subjects affected / exposed | 2 / 124 (1.61%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Dermatitis contact | | | |
| subjects affected / exposed | 1 / 124 (0.81%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dermatitis diaper | | | |
| subjects affected / exposed | 1 / 124 (0.81%) | 1 / 112 (0.89%) | 0 / 179 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Eczema | | | |
| subjects affected / exposed | 1 / 124 (0.81%) | 2 / 112 (1.79%) | 0 / 179 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Skin disorder | | | |
| subjects affected / exposed | 1 / 124 (0.81%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dermatitis atopic | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ingrowing nail | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acne | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acanthosis nigricans | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tenderness (any) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |

| | | | |
|---|--|------------------|-------------------|
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[9]</p> <p>occurrences (all)</p> | 55 / 108 (50.93%) | 50 / 87 (57.47%) | 96 / 155 (61.94%) |
| Tenderness (significant) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[10]</p> <p>occurrences (all)</p> | 7 / 92 (7.61%) | 6 / 68 (8.82%) | 15 / 141 (10.64%) |
| Swelling (any) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[11]</p> <p>occurrences (all)</p> | 25 / 97 (25.77%) | 17 / 73 (23.29%) | 32 / 144 (22.22%) |
| Swelling (mild) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[12]</p> <p>occurrences (all)</p> | 20 / 94 (21.28%) | 16 / 72 (22.22%) | 29 / 143 (20.28%) |
| Swelling (moderate) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[13]</p> <p>occurrences (all)</p> | 9 / 94 (9.57%) | 2 / 69 (2.90%) | 8 / 141 (5.67%) |
| Swelling (severe) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> | | | |

| | | | |
|--|--|------------------|-------------------|
| subjects affected / exposed ^[14] | 0 / 90 (0.00%) | 0 / 68 (0.00%) | 0 / 138 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Redness (any) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[15] | 41 / 103 (39.81%) | 27 / 76 (35.53%) | 52 / 149 (34.90%) |
| occurrences (all) | 41 | 27 | 52 |
| Redness (mild) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[16] | 31 / 99 (31.31%) | 25 / 74 (33.78%) | 46 / 146 (31.51%) |
| occurrences (all) | 31 | 25 | 46 |
| Redness (moderate) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[17] | 12 / 94 (12.77%) | 5 / 70 (7.14%) | 14 / 142 (9.86%) |
| occurrences (all) | 12 | 5 | 14 |
| Redness (severe) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[18] | 0 / 90 (0.00%) | 0 / 68 (0.00%) | 0 / 138 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| Dysuria | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematuria | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |

| | | | |
|---|-------------------------|----------------------|------------------------|
| Pain in extremity subjects affected / exposed occurrences (all) | 0 / 124 (0.00%) 0 | 0 / 112 (0.00%) 0 | 0 / 179 (0.00%) 0 |
| Back pain subjects affected / exposed occurrences (all) | 0 / 124 (0.00%) 0 | 0 / 112 (0.00%) 0 | 0 / 179 (0.00%) 0 |
| Neck pain subjects affected / exposed occurrences (all) | 0 / 124 (0.00%) 0 | 0 / 112 (0.00%) 0 | 0 / 179 (0.00%) 0 |
| Torticollis subjects affected / exposed occurrences (all) | 0 / 124 (0.00%) 0 | 0 / 112 (0.00%) 0 | 0 / 179 (0.00%) 0 |
| Musculoskeletal chest pain subjects affected / exposed occurrences (all) | 0 / 124 (0.00%) 0 | 0 / 112 (0.00%) 0 | 0 / 179 (0.00%) 0 |
| Infections and infestations | | | |
| Otitis media subjects affected / exposed occurrences (all) | 15 / 124 (12.10%) 17 | 5 / 112 (4.46%) 5 | 12 / 179 (6.70%) 12 |
| Upper respiratory tract infection subjects affected / exposed occurrences (all) | 9 / 124 (7.26%) 9 | 9 / 112 (8.04%) 9 | 3 / 179 (1.68%) 3 |
| Nasopharyngitis subjects affected / exposed occurrences (all) | 4 / 124 (3.23%) 4 | 1 / 112 (0.89%) 1 | 1 / 179 (0.56%) 1 |
| Sinusitis subjects affected / exposed occurrences (all) | 3 / 124 (2.42%) 3 | 3 / 112 (2.68%) 3 | 4 / 179 (2.23%) 4 |
| Rhinitis subjects affected / exposed occurrences (all) | 3 / 124 (2.42%) 3 | 0 / 112 (0.00%) 0 | 2 / 179 (1.12%) 2 |
| Otitis media acute subjects affected / exposed occurrences (all) | 3 / 124 (2.42%) 3 | 1 / 112 (0.89%) 1 | 0 / 179 (0.00%) 0 |
| Viral infection | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 2 / 124 (1.61%) | 1 / 112 (0.89%) | 5 / 179 (2.79%) |
| occurrences (all) | 2 | 1 | 5 |
| Croup infectious | | | |
| subjects affected / exposed | 2 / 124 (1.61%) | 1 / 112 (0.89%) | 2 / 179 (1.12%) |
| occurrences (all) | 2 | 1 | 2 |
| Gastroenteritis | | | |
| subjects affected / exposed | 2 / 124 (1.61%) | 0 / 112 (0.00%) | 2 / 179 (1.12%) |
| occurrences (all) | 2 | 0 | 2 |
| Pharyngitis | | | |
| subjects affected / exposed | 2 / 124 (1.61%) | 0 / 112 (0.00%) | 1 / 179 (0.56%) |
| occurrences (all) | 2 | 0 | 1 |
| Ear infection | | | |
| subjects affected / exposed | 2 / 124 (1.61%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 2 / 124 (1.61%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 1 / 124 (0.81%) | 1 / 112 (0.89%) | 3 / 179 (1.68%) |
| occurrences (all) | 1 | 1 | 3 |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 124 (0.81%) | 1 / 112 (0.89%) | 1 / 179 (0.56%) |
| occurrences (all) | 1 | 1 | 1 |
| Bronchiolitis | | | |
| subjects affected / exposed | 1 / 124 (0.81%) | 1 / 112 (0.89%) | 0 / 179 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Eye infection | | | |
| subjects affected / exposed | 1 / 124 (0.81%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Impetigo | | | |
| subjects affected / exposed | 1 / 124 (0.81%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Influenza | | | |
| subjects affected / exposed | 1 / 124 (0.81%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Lice infestation | | | |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 124 (0.81%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Otitis media chronic | | | |
| subjects affected / exposed | 1 / 124 (0.81%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Paronychia | | | |
| subjects affected / exposed | 1 / 124 (0.81%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pneumonia viral | | | |
| subjects affected / exposed | 1 / 124 (0.81%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 1 / 124 (0.81%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Skin infection | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 1 / 179 (0.56%) |
| occurrences (all) | 0 | 0 | 1 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 1 / 179 (0.56%) |
| occurrences (all) | 0 | 0 | 1 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 1 / 179 (0.56%) |
| occurrences (all) | 0 | 0 | 1 |
| Cellulitis streptococcal | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 1 / 112 (0.89%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Coxsackie viral infection | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 1 / 112 (0.89%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dermatitis infected | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 1 / 112 (0.89%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pharyngitis streptococcal | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 1 / 112 (0.89%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Viral rash | | | |

| | | | |
|---------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 124 (0.00%) | 1 / 112 (0.89%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Intertrigo candida | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urethritis | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis externa | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema infectiosum | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Folliculitis | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand-foot-and-mouth disease | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral herpes | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acarodermatitis | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatophytosis | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Viral pharyngitis | | | |

| | | | |
|------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acute sinusitis | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Furuncle | | | |
| subjects affected / exposed | 0 / 124 (0.00%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Anorexia | | | |
| subjects affected / exposed | 1 / 124 (0.81%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Lactose intolerance | | | |
| subjects affected / exposed | 1 / 124 (0.81%) | 0 / 112 (0.00%) | 0 / 179 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| Non-serious adverse events | 13vPnC Group 1 (Cohort 2) Dose 1 | 13vPnC Group 1 (Cohort 2) Dose 2 | 13vPnC Group 2 (Cohort 2) Dose 1 |
|---|-------------------------------------|-------------------------------------|-------------------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 134 / 175 (76.57%) | 99 / 165 (60.00%) | 74 / 118 (62.71%) |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 7 / 175 (4.00%) | 5 / 165 (3.03%) | 4 / 118 (3.39%) |
| occurrences (all) | 7 | 5 | 5 |
| Injection site pruritus | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza like illness | | | |
| subjects affected / exposed | 1 / 175 (0.57%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Injection site reaction | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 1 / 118 (0.85%) |
| occurrences (all) | 0 | 0 | 1 |
| Chills | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain | | | |

| | | | |
|--|--|-------------------------|-------------------------|
| subjects affected / exposed occurrences (all) | 0 / 175 (0.00%) 0 | 0 / 165 (0.00%) 0 | 0 / 118 (0.00%) 0 |
| Injection site pain subjects affected / exposed occurrences (all) | 0 / 175 (0.00%) 0 | 0 / 165 (0.00%) 0 | 0 / 118 (0.00%) 0 |
| Fever >=38 degrees C but <=39 degrees C | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[1] occurrences (all) | 24 / 137 (17.52%) 24 | 12 / 101 (11.88%) 12 | 13 / 90 (14.44%) 13 |
| Fever >39 degrees C but <=40 degrees C | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative assessment type: Systematic subjects affected / exposed ^[2] occurrences (all) | 6 / 130 (4.62%) 6 | 2 / 100 (2.00%) 2 | 3 / 89 (3.37%) 3 |
| Fever >40 degrees C | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[3] occurrences (all) | 0 / 130 (0.00%) 0 | 1 / 98 (1.02%) 1 | 1 / 88 (1.14%) 1 |
| Decreased appetite | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[4] occurrences (all) | 58 / 146 (39.73%) 58 | 39 / 113 (34.51%) 39 | 32 / 94 (34.04%) 32 |
| Irritability | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[5] occurrences (all) | 113 / 156 (72.44%) 113 | 77 / 126 (61.11%) 77 | 53 / 102 (51.96%) 53 |

| | | | |
|---|--|-------------------|------------------|
| Increased sleep | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| | alternative dictionary used: Systemic Events 0.0 | | |
| | alternative assessment type: Systematic | | |
| subjects affected / exposed ^[6] | 54 / 146 (36.99%) | 26 / 109 (23.85%) | 23 / 97 (23.71%) |
| occurrences (all) | 54 | 26 | 23 |
| Decreased sleep | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| | alternative dictionary used: Systemic Events 0.0 | | |
| | alternative assessment type: Systematic | | |
| subjects affected / exposed ^[7] | 45 / 140 (32.14%) | 30 / 112 (26.79%) | 17 / 91 (18.68%) |
| occurrences (all) | 45 | 30 | 17 |
| Hives (urticaria) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| | alternative dictionary used: Systemic Events 0.0 | | |
| | alternative assessment type: Systematic | | |
| subjects affected / exposed ^[8] | 2 / 131 (1.53%) | 0 / 98 (0.00%) | 4 / 88 (4.55%) |
| occurrences (all) | 2 | 0 | 4 |
| Immune system disorders | | | |
| | Drug hypersensitivity | | |
| | subjects affected / exposed | 1 / 175 (0.57%) | 0 / 165 (0.00%) |
| | occurrences (all) | 2 | 0 |
| Seasonal allergy | | | |
| | subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) |
| | occurrences (all) | 0 | 0 |
| Reproductive system and breast disorders | | | |
| | Vulvovaginal discomfort | | |
| | subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) |
| | occurrences (all) | 0 | 1 |
| | Penile adhesion | | |
| | subjects affected / exposed | 0 / 175 (0.00%) | 0 / 118 (0.00%) |
| Respiratory, thoracic and mediastinal disorders | | | |
| | occurrences (all) | 0 | 0 |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| Cough | | | |
| subjects affected / exposed | 6 / 175 (3.43%) | 7 / 165 (4.24%) | 3 / 118 (2.54%) |
| occurrences (all) | 6 | 7 | 4 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 5 / 175 (2.86%) | 4 / 165 (2.42%) | 3 / 118 (2.54%) |
| occurrences (all) | 5 | 4 | 4 |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal congestion | | | |
| subjects affected / exposed | 2 / 175 (1.14%) | 2 / 165 (1.21%) | 1 / 118 (0.85%) |
| occurrences (all) | 2 | 2 | 1 |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus congestion | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wheezing | | | |
| subjects affected / exposed | 1 / 175 (0.57%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 1 / 165 (0.61%) | 3 / 118 (2.54%) |
| occurrences (all) | 0 | 1 | 3 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 1 / 175 (0.57%) | 1 / 165 (0.61%) | 0 / 118 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Rhinitis allergic | | | |
| subjects affected / exposed | 2 / 175 (1.14%) | 1 / 165 (0.61%) | 0 / 118 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Bronchospasm | | | |
| subjects affected / exposed | 1 / 175 (0.57%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Interstitial lung disease | | | |
| subjects affected / exposed | 1 / 175 (0.57%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|----------------------|----------------------|----------------------|
| Bronchial hyperreactivity subjects affected / exposed occurrences (all) | 0 / 175 (0.00%) 0 | 1 / 165 (0.61%) 1 | 1 / 118 (0.85%) 1 |
| Paranasal sinus hypersecretion subjects affected / exposed occurrences (all) | 0 / 175 (0.00%) 0 | 1 / 165 (0.61%) 1 | 0 / 118 (0.00%) 0 |
| Sneezing subjects affected / exposed occurrences (all) | 0 / 175 (0.00%) 0 | 0 / 165 (0.00%) 0 | 0 / 118 (0.00%) 0 |
| Psychiatric disorders | | | |
| Breath holding subjects affected / exposed occurrences (all) | 1 / 175 (0.57%) 1 | 0 / 165 (0.00%) 0 | 0 / 118 (0.00%) 0 |
| Sleep disorder subjects affected / exposed occurrences (all) | 1 / 175 (0.57%) 1 | 0 / 165 (0.00%) 0 | 0 / 118 (0.00%) 0 |
| Asperger's disorder subjects affected / exposed occurrences (all) | 0 / 175 (0.00%) 0 | 0 / 165 (0.00%) 0 | 0 / 118 (0.00%) 0 |
| Attention deficit/hyperactivity disorder subjects affected / exposed occurrences (all) | 0 / 175 (0.00%) 0 | 0 / 165 (0.00%) 0 | 0 / 118 (0.00%) 0 |
| Anxiety subjects affected / exposed occurrences (all) | 0 / 175 (0.00%) 0 | 0 / 165 (0.00%) 0 | 0 / 118 (0.00%) 0 |
| Depression subjects affected / exposed occurrences (all) | 0 / 175 (0.00%) 0 | 0 / 165 (0.00%) 0 | 0 / 118 (0.00%) 0 |
| Investigations | | | |
| Cardiac murmur subjects affected / exposed occurrences (all) | 0 / 175 (0.00%) 0 | 1 / 165 (0.61%) 1 | 0 / 118 (0.00%) 0 |
| Heart rate decreased subjects affected / exposed occurrences (all) | 0 / 175 (0.00%) 0 | 0 / 165 (0.00%) 0 | 0 / 118 (0.00%) 0 |
| Injury, poisoning and procedural complications | | | |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| Skin laceration | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 1 / 165 (0.61%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Excoriation | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lower limb fracture | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Head injury | | | |
| subjects affected / exposed | 1 / 175 (0.57%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Laceration | | | |
| subjects affected / exposed | 1 / 175 (0.57%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Mouth injury | | | |
| subjects affected / exposed | 1 / 175 (0.57%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Burns second degree | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 1 / 118 (0.85%) |
| occurrences (all) | 0 | 0 | 1 |
| Traumatic brain injury | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 1 / 165 (0.61%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Ulna fracture | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 1 / 165 (0.61%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye injury | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand fracture | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|-------------------------------|-----------------|-----------------|-----------------|
| Periorbital haematoma | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Foot fracture | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Limb injury | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle strain | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wrist fracture | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 2 / 118 (1.69%) |
| occurrences (all) | 0 | 0 | 2 |
| Speech disorder developmental | | | |
| subjects affected / exposed | 1 / 175 (0.57%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Presyncope | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dizziness | | | |

| | | | |
|---|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 175 (0.00%) 0 | 0 / 165 (0.00%) 0 | 0 / 118 (0.00%) 0 |
| Migraine subjects affected / exposed occurrences (all) | 0 / 175 (0.00%) 0 | 0 / 165 (0.00%) 0 | 0 / 118 (0.00%) 0 |
| Somnolence subjects affected / exposed occurrences (all) | 0 / 175 (0.00%) 0 | 0 / 165 (0.00%) 0 | 0 / 118 (0.00%) 0 |
| Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all) | 1 / 175 (0.57%) 1 | 1 / 165 (0.61%) 1 | 0 / 118 (0.00%) 0 |
| Leukocytosis subjects affected / exposed occurrences (all) | 1 / 175 (0.57%) 1 | 0 / 165 (0.00%) 0 | 0 / 118 (0.00%) 0 |
| Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all) | 3 / 175 (1.71%) 3 | 1 / 165 (0.61%) 1 | 0 / 118 (0.00%) 0 |
| Eustachian tube dysfunction subjects affected / exposed occurrences (all) | 0 / 175 (0.00%) 0 | 0 / 165 (0.00%) 0 | 0 / 118 (0.00%) 0 |
| Eye disorders Conjunctivitis subjects affected / exposed occurrences (all) | 2 / 175 (1.14%) 2 | 3 / 165 (1.82%) 3 | 0 / 118 (0.00%) 0 |
| Hypermetropia subjects affected / exposed occurrences (all) | 0 / 175 (0.00%) 0 | 0 / 165 (0.00%) 0 | 1 / 118 (0.85%) 1 |
| Eye swelling subjects affected / exposed occurrences (all) | 0 / 175 (0.00%) 0 | 1 / 165 (0.61%) 1 | 0 / 118 (0.00%) 0 |
| Lacrimation increased subjects affected / exposed occurrences (all) | 0 / 175 (0.00%) 0 | 1 / 165 (0.61%) 1 | 0 / 118 (0.00%) 0 |
| Myopia | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 175 (0.00%) 0 | 0 / 165 (0.00%) 0 | 0 / 118 (0.00%) 0 |
| Gastrointestinal disorders | | | |
| Vomiting | | | |
| subjects affected / exposed | 2 / 175 (1.14%) | 3 / 165 (1.82%) | 3 / 118 (2.54%) |
| occurrences (all) | 2 | 3 | 3 |
| Diarrhoea | | | |
| subjects affected / exposed | 6 / 175 (3.43%) | 3 / 165 (1.82%) | 2 / 118 (1.69%) |
| occurrences (all) | 6 | 3 | 2 |
| Constipation | | | |
| subjects affected / exposed | 2 / 175 (1.14%) | 1 / 165 (0.61%) | 1 / 118 (0.85%) |
| occurrences (all) | 2 | 1 | 1 |
| Tongue coated | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Duodenogastric reflux | | | |
| subjects affected / exposed | 1 / 175 (0.57%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 2 / 165 (1.21%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Lip dry | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 1 / 165 (0.61%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Teething | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 1 / 165 (0.61%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritable bowel syndrome | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| Toothache | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Uvulitis | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Rash | | | |
| subjects affected / exposed | 5 / 175 (2.86%) | 0 / 165 (0.00%) | 1 / 118 (0.85%) |
| occurrences (all) | 5 | 0 | 1 |
| Dermatitis | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis contact | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis diaper | | | |
| subjects affected / exposed | 6 / 175 (3.43%) | 1 / 165 (0.61%) | 0 / 118 (0.00%) |
| occurrences (all) | 6 | 1 | 0 |
| Eczema | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 1 / 165 (0.61%) | 1 / 118 (0.85%) |
| occurrences (all) | 0 | 1 | 1 |
| Skin disorder | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis atopic | | | |
| subjects affected / exposed | 1 / 175 (0.57%) | 1 / 165 (0.61%) | 0 / 118 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 1 / 165 (0.61%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Ingrowing nail | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 1 / 165 (0.61%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Acne | | | |

| | | | |
|--|--|-------------------|-------------------|
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acanthosis nigricans | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tenderness (any) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[9] | 67 / 148 (45.27%) | 69 / 125 (55.20%) | 64 / 102 (62.75%) |
| occurrences (all) | 67 | 69 | 64 |
| Tenderness (significant) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[10] | 7 / 133 (5.26%) | 10 / 101 (9.90%) | 12 / 92 (13.04%) |
| occurrences (all) | 7 | 10 | 12 |
| Swelling (any) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[11] | 25 / 142 (17.61%) | 18 / 105 (17.14%) | 18 / 90 (20.00%) |
| occurrences (all) | 25 | 18 | 18 |
| Swelling (mild) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[12] | 20 / 141 (14.18%) | 16 / 104 (15.38%) | 12 / 89 (13.48%) |
| occurrences (all) | 20 | 16 | 12 |
| Swelling (moderate) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|--|--|-------------------|------------------|
| subjects affected / exposed ^[13] | 10 / 135 (7.41%) | 8 / 102 (7.84%) | 10 / 89 (11.24%) |
| occurrences (all) | 10 | 8 | 10 |
| Swelling (severe) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[14] | 0 / 131 (0.00%) | 0 / 98 (0.00%) | 1 / 88 (1.14%) |
| occurrences (all) | 0 | 0 | 1 |
| Redness (any) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[15] | 27 / 143 (18.88%) | 26 / 110 (23.64%) | 33 / 91 (36.26%) |
| occurrences (all) | 27 | 26 | 33 |
| Redness (mild) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[16] | 24 / 143 (16.78%) | 20 / 108 (18.52%) | 28 / 90 (31.11%) |
| occurrences (all) | 24 | 20 | 28 |
| Redness (moderate) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[17] | 8 / 135 (5.93%) | 6 / 100 (6.00%) | 13 / 89 (14.61%) |
| occurrences (all) | 8 | 6 | 13 |
| Redness (severe) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[18] | 1 / 131 (0.76%) | 0 / 98 (0.00%) | 1 / 88 (1.14%) |
| occurrences (all) | 1 | 0 | 1 |
| Renal and urinary disorders | | | |

| | | | |
|---|------------------|------------------|-----------------|
| Dysuria | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 1 / 118 (0.85%) |
| occurrences (all) | 0 | 0 | 1 |
| Haematuria | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 1 / 118 (0.85%) |
| occurrences (all) | 0 | 0 | 1 |
| Back pain | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Torticollis | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Otitis media | | | |
| subjects affected / exposed | 12 / 175 (6.86%) | 11 / 165 (6.67%) | 1 / 118 (0.85%) |
| occurrences (all) | 12 | 11 | 1 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 15 / 175 (8.57%) | 14 / 165 (8.48%) | 1 / 118 (0.85%) |
| occurrences (all) | 16 | 14 | 1 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 7 / 175 (4.00%) | 2 / 165 (1.21%) | 3 / 118 (2.54%) |
| occurrences (all) | 7 | 2 | 3 |
| Sinusitis | | | |
| subjects affected / exposed | 4 / 175 (2.29%) | 1 / 165 (0.61%) | 2 / 118 (1.69%) |
| occurrences (all) | 5 | 1 | 2 |
| Rhinitis | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 8 / 175 (4.57%) | 3 / 165 (1.82%) | 0 / 118 (0.00%) |
| occurrences (all) | 10 | 3 | 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 1 / 175 (0.57%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Viral infection | | | |
| subjects affected / exposed | 4 / 175 (2.29%) | 3 / 165 (1.82%) | 3 / 118 (2.54%) |
| occurrences (all) | 4 | 3 | 3 |
| Croup infectious | | | |
| subjects affected / exposed | 7 / 175 (4.00%) | 1 / 165 (0.61%) | 1 / 118 (0.85%) |
| occurrences (all) | 7 | 1 | 1 |
| Gastroenteritis | | | |
| subjects affected / exposed | 2 / 175 (1.14%) | 1 / 165 (0.61%) | 0 / 118 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 1 / 165 (0.61%) | 3 / 118 (2.54%) |
| occurrences (all) | 0 | 1 | 3 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 1 / 165 (0.61%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 1 / 165 (0.61%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 2 / 175 (1.14%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 3 / 175 (1.71%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 5 | 0 | 0 |
| Bronchiolitis | | | |
| subjects affected / exposed | 2 / 175 (1.14%) | 1 / 165 (0.61%) | 0 / 118 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Eye infection | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Impetigo | | | |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 175 (0.00%) | 1 / 165 (0.61%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Influenza | | | |
| subjects affected / exposed | 2 / 175 (1.14%) | 0 / 165 (0.00%) | 2 / 118 (1.69%) |
| occurrences (all) | 2 | 0 | 2 |
| Lice infestation | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media chronic | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 1 / 165 (0.61%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Paronychia | | | |
| subjects affected / exposed | 1 / 175 (0.57%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pneumonia viral | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin infection | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cellulitis streptococcal | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Coxsackie viral infection | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis infected | | | |

| | | | |
|---------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngitis streptococcal | | | |
| subjects affected / exposed | 2 / 175 (1.14%) | 1 / 165 (0.61%) | 0 / 118 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Viral rash | | | |
| subjects affected / exposed | 1 / 175 (0.57%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Intertrigo candida | | | |
| subjects affected / exposed | 1 / 175 (0.57%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 1 / 175 (0.57%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Urethritis | | | |
| subjects affected / exposed | 1 / 175 (0.57%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Otitis externa | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 1 / 118 (0.85%) |
| occurrences (all) | 0 | 0 | 1 |
| Erythema infectiosum | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 2 / 165 (1.21%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Folliculitis | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 1 / 165 (0.61%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hand-foot-and-mouth disease | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 1 / 165 (0.61%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 1 / 165 (0.61%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oral herpes | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 1 / 165 (0.61%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Acarodermatitis | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatophytosis | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Viral pharyngitis | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acute sinusitis | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Furuncle | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Anorexia | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lactose intolerance | | | |
| subjects affected / exposed | 0 / 175 (0.00%) | 0 / 165 (0.00%) | 0 / 118 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| Non-serious adverse events | 6-Month Follow-up 13vPnC Group 1 (Cohort 1 and 2) | 6-Month Follow-up 13vPnC Group 2 (Cohort 1 and 2) | 13vPnC Group 3 |
|--|---|---|--------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 2 / 299 (0.67%) | 2 / 297 (0.67%) | 242 / 294 (82.31%) |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 7 / 294 (2.38%) |
| occurrences (all) | 0 | 0 | 7 |
| Injection site pruritus | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza like illness | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site reaction | | | |

| | | | |
|---|--|-----------------|-------------------|
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site pain | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fever >=38 degrees C but <=39 degrees C | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[1] | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 9 / 212 (4.25%) |
| occurrences (all) | 0 | 0 | 9 |
| Fever >39 degrees C but <=40 degrees C | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[2] | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 5 / 212 (2.36%) |
| occurrences (all) | 0 | 0 | 5 |
| Fever >40 degrees C | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[3] | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 1 / 210 (0.48%) |
| occurrences (all) | 0 | 0 | 1 |
| Decreased appetite | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[4] | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 52 / 227 (22.91%) |
| occurrences (all) | 0 | 0 | 52 |

| | | | |
|--|--|-----------------|-------------------|
| Irritability | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| | alternative dictionary used: Systemic Events 0.0 | | |
| | alternative assessment type: Systematic | | |
| | subjects affected / exposed ^[5] | 0 / 299 (0.00%) | 0 / 297 (0.00%) |
| Increased sleep | occurrences (all) | 0 | 73 / 234 (31.20%) |
| | | 0 | 73 |
| | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| | alternative dictionary used: Systemic Events 0.0 | | |
| Decreased sleep | alternative assessment type: Systematic | | |
| | subjects affected / exposed ^[6] | 0 / 299 (0.00%) | 0 / 297 (0.00%) |
| | occurrences (all) | 0 | 48 / 226 (21.24%) |
| | | 0 | 48 |
| Hives (urticaria) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| | alternative dictionary used: Systemic Events 0.0 | | |
| | alternative assessment type: Systematic | | |
| | subjects affected / exposed ^[7] | 0 / 299 (0.00%) | 0 / 297 (0.00%) |
| Hives (urticaria) | occurrences (all) | 0 | 12 / 212 (5.66%) |
| | | 0 | 12 |
| | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| | alternative dictionary used: Systemic Events 0.0 | | |
| Immune system disorders | alternative assessment type: Systematic | | |
| | subjects affected / exposed ^[8] | 0 / 299 (0.00%) | 0 / 297 (0.00%) |
| | occurrences (all) | 0 | 4 / 213 (1.88%) |
| | | 0 | 4 |
| Drug hypersensitivity | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| | subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) |
| | occurrences (all) | 0 | 0 / 294 (0.00%) |
| | | 0 | 0 |
| Seasonal allergy | subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) |
| | occurrences (all) | 0 | 1 / 294 (0.34%) |
| | | 0 | 1 |
| | | | |
| Reproductive system and breast disorders | | | |
| | Vulvovaginal discomfort | | |

| | | | |
|---|-----------------|-----------------|------------------|
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Penile adhesion | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 10 / 294 (3.40%) |
| occurrences (all) | 0 | 0 | 10 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 1 / 294 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 1 / 294 (0.34%) |
| occurrences (all) | 0 | 0 | 2 |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 3 / 294 (1.02%) |
| occurrences (all) | 0 | 0 | 3 |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus congestion | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wheezing | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 1 / 294 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Asthma | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 1 / 294 (0.34%) |
| occurrences (all) | 0 | 0 | 2 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis allergic | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 299 (0.33%) | 1 / 297 (0.34%) | 0 / 294 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Bronchospasm | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Interstitial lung disease | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paranasal sinus hypersecretion | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sneezing | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 1 / 294 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Psychiatric disorders | | | |
| Breath holding | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sleep disorder | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 1 / 297 (0.34%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Asperger's disorder | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 1 / 297 (0.34%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Attention deficit/hyperactivity disorder | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 1 / 297 (0.34%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Anxiety | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Depression | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 0 / 294 (0.00%) 0 |
| Investigations | | | |
| Cardiac murmur | | | |
| subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 0 / 294 (0.00%) 0 |
| Heart rate decreased | | | |
| subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 0 / 294 (0.00%) 0 |
| Injury, poisoning and procedural complications | | | |
| Skin laceration | | | |
| subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 0 / 294 (0.00%) 0 |
| Excoriation | | | |
| subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 0 / 294 (0.00%) 0 |
| Lower limb fracture | | | |
| subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 0 / 294 (0.00%) 0 |
| Head injury | | | |
| subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 1 / 294 (0.34%) 1 |
| Laceration | | | |
| subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 0 / 294 (0.00%) 0 |
| Mouth injury | | | |
| subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 0 / 294 (0.00%) 0 |
| Burns second degree | | | |
| subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 0 / 294 (0.00%) 0 |
| Traumatic brain injury | | | |
| subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 0 / 294 (0.00%) 0 |
| Ulna fracture | | | |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 1 / 294 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Eye injury | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 1 / 294 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Hand fracture | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 1 / 294 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Periorbital haematoma | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 1 / 294 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Foot fracture | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Limb injury | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle strain | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wrist fracture | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 3 / 294 (1.02%) |
| occurrences (all) | 0 | 0 | 3 |

| | | | |
|---|----------------------|----------------------|----------------------|
| Speech disorder developmental subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 0 / 294 (0.00%) 0 |
| Presyncope subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 1 / 294 (0.34%) 1 |
| Syncope subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 1 / 294 (0.34%) 1 |
| Dizziness subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 0 / 294 (0.00%) 0 |
| Migraine subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 0 / 294 (0.00%) 0 |
| Somnolence subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 0 / 294 (0.00%) 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 0 / 294 (0.00%) 0 |
| Leukocytosis subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 0 / 294 (0.00%) 0 |
| Ear and labyrinth disorders | | | |
| Ear pain subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 1 / 294 (0.34%) 1 |
| Eustachian tube dysfunction subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 0 / 294 (0.00%) 0 |
| Eye disorders | | | |
| Conjunctivitis subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 2 / 294 (0.68%) 2 |
| Hypermetropia | | | |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye swelling | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lacrimation increased | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myopia | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Vomiting | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 8 / 294 (2.72%) |
| occurrences (all) | 0 | 0 | 9 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 3 / 294 (1.02%) |
| occurrences (all) | 0 | 0 | 3 |
| Constipation | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tongue coated | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Duodenogastric reflux | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 1 / 294 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Lip dry | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Teething | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|----------------------|----------------------|----------------------|
| Abdominal pain upper subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 1 / 294 (0.34%) 1 |
| Nausea subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 1 / 294 (0.34%) 1 |
| Irritable bowel syndrome subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 0 / 294 (0.00%) 0 |
| Toothache subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 0 / 294 (0.00%) 0 |
| Uvulitis subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 0 / 294 (0.00%) 0 |
| Skin and subcutaneous tissue disorders | | | |
| Rash subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 0 / 294 (0.00%) 0 |
| Dermatitis subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 0 / 294 (0.00%) 0 |
| Dermatitis contact subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 0 / 294 (0.00%) 0 |
| Dermatitis diaper subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 0 / 294 (0.00%) 0 |
| Eczema subjects affected / exposed occurrences (all) | 1 / 299 (0.33%) 1 | 0 / 297 (0.00%) 0 | 1 / 294 (0.34%) 1 |
| Skin disorder subjects affected / exposed occurrences (all) | 0 / 299 (0.00%) 0 | 0 / 297 (0.00%) 0 | 0 / 294 (0.00%) 0 |
| Dermatitis atopic | | | |

| | | | |
|--|--|-----------------|--------------------|
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ingrowing nail | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acne | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acanthosis nigricans | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tenderness (any) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[9] | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 230 / 265 (86.79%) |
| occurrences (all) | 0 | 0 | 230 |
| Tenderness (significant) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[10] | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 43 / 221 (19.46%) |
| occurrences (all) | 0 | 0 | 43 |
| Swelling (any) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[11] | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 85 / 226 (37.61%) |
| occurrences (all) | 0 | 0 | 85 |
| Swelling (mild) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local | | | |

| | | | |
|---|--|-----------------|--------------------|
| Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[12] | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 48 / 220 (21.82%) |
| occurrences (all) | 0 | 0 | 48 |
| Swelling (moderate) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[13] | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 48 / 219 (21.92%) |
| occurrences (all) | 0 | 0 | 48 |
| Swelling (severe) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[14] | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 7 / 211 (3.32%) |
| occurrences (all) | 0 | 0 | 7 |
| Redness (any) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[15] | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 100 / 233 (42.92%) |
| occurrences (all) | 0 | 0 | 100 |
| Redness (mild) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[16] | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 63 / 226 (27.88%) |
| occurrences (all) | 0 | 0 | 63 |
| Redness (moderate) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|--|--|-----------------|-------------------|
| subjects affected / exposed ^[17] | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 48 / 218 (22.02%) |
| occurrences (all) | 0 | 0 | 48 |
| Redness (severe) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[18] | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 7 / 212 (3.30%) |
| occurrences (all) | 0 | 0 | 7 |
| Renal and urinary disorders | | | |
| Dysuria | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 1 / 294 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Haematuria | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 1 / 294 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Musculoskeletal and connective tissue disorders | | | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Back pain | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 1 / 294 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 1 / 294 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Torticollis | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 1 / 294 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Otitis media | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 3 / 294 (1.02%) |
| occurrences (all) | 0 | 0 | 3 |
| Upper respiratory tract infection | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 2 / 294 (0.68%) |
| occurrences (all) | 0 | 0 | 2 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 3 / 294 (1.02%) |
| occurrences (all) | 0 | 0 | 3 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 3 / 294 (1.02%) |
| occurrences (all) | 0 | 0 | 3 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 3 / 294 (1.02%) |
| occurrences (all) | 0 | 0 | 3 |
| Croup infectious | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 2 / 294 (0.68%) |
| occurrences (all) | 0 | 0 | 2 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 2 / 294 (0.68%) |
| occurrences (all) | 0 | 0 | 2 |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 1 / 294 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Bronchitis | | | |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye infection | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Impetigo | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 3 / 294 (1.02%) |
| occurrences (all) | 0 | 0 | 3 |
| Lice infestation | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media chronic | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia viral | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin infection | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract infection | | | |

| | | | |
|---------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cellulitis streptococcal | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Coxsackie viral infection | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis infected | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngitis streptococcal | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 6 / 294 (2.04%) |
| occurrences (all) | 0 | 0 | 6 |
| Viral rash | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intertrigo candida | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urethritis | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis externa | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema infectiosum | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Folliculitis | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand-foot-and-mouth disease | | | |

| | | | |
|------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral herpes | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acarodermatitis | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 1 / 294 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Dermatophytosis | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 1 / 294 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Viral pharyngitis | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 1 / 294 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Acute sinusitis | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Furuncle | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Anorexia | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lactose intolerance | | | |
| subjects affected / exposed | 0 / 299 (0.00%) | 0 / 297 (0.00%) | 0 / 294 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| Non-serious adverse events | 6-Month Follow-up 13vPnC Group 3 | 13vPnC Group 4 | 6-Month Follow-up 13vPnC Group 4 |
|--|-------------------------------------|--------------------|-------------------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 7 / 294 (2.38%) | 258 / 298 (86.58%) | 4 / 298 (1.34%) |
| General disorders and administration site conditions | | | |

| | | | |
|---|--|------------------|-----------------|
| Pyrexia | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 3 / 298 (1.01%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Injection site pruritus | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 1 / 298 (0.34%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Influenza like illness | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 1 / 298 (0.34%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Injection site reaction | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 2 / 298 (0.67%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 2 / 298 (0.67%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Injection site pain | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 1 / 298 (0.34%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Fever >=38 degrees C but <=39 degrees C | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[1] | 0 / 294 (0.00%) | 11 / 214 (5.14%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 11 | 0 |
| Fever >39 degrees C but <=40 degrees C | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[2] | 0 / 294 (0.00%) | 1 / 212 (0.47%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Fever >40 degrees C | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |

| | | | |
|--|---|------------------------------------|---------------------------------|
| <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[3]</p> <p>occurrences (all)</p> | <p>0 / 294 (0.00%)</p> <p>0</p> | <p>1 / 212 (0.47%)</p> <p>1</p> | <p>0 / 298 (0.00%)</p> <p>0</p> |
| Decreased appetite | <p>Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.</p> | | |
| <p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[4]</p> <p>occurrences (all)</p> | <p>0 / 294 (0.00%)</p> <p>0</p> | <p>51 / 223 (22.87%)</p> <p>51</p> | <p>0 / 298 (0.00%)</p> <p>0</p> |
| Irritability | <p>Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.</p> | | |
| <p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[5]</p> <p>occurrences (all)</p> | <p>0 / 294 (0.00%)</p> <p>0</p> | <p>59 / 234 (25.21%)</p> <p>59</p> | <p>0 / 298 (0.00%)</p> <p>0</p> |
| Increased sleep | <p>Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.</p> | | |
| <p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[6]</p> <p>occurrences (all)</p> | <p>0 / 294 (0.00%)</p> <p>0</p> | <p>61 / 229 (26.64%)</p> <p>61</p> | <p>0 / 298 (0.00%)</p> <p>0</p> |
| Decreased sleep | <p>Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.</p> | | |
| <p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[7]</p> <p>occurrences (all)</p> | <p>0 / 294 (0.00%)</p> <p>0</p> | <p>42 / 224 (18.75%)</p> <p>42</p> | <p>0 / 298 (0.00%)</p> <p>0</p> |
| Hives (urticaria) | <p>Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.</p> | | |
| <p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[8]</p> <p>occurrences (all)</p> | <p>0 / 294 (0.00%)</p> <p>0</p> | <p>3 / 214 (1.40%)</p> <p>3</p> | <p>0 / 298 (0.00%)</p> <p>0</p> |
| Immune system disorders | | | |

| | | | |
|---|----------------------|----------------------|----------------------|
| Drug hypersensitivity subjects affected / exposed occurrences (all) | 0 / 294 (0.00%) 0 | 0 / 298 (0.00%) 0 | 0 / 298 (0.00%) 0 |
| Seasonal allergy subjects affected / exposed occurrences (all) | 0 / 294 (0.00%) 0 | 0 / 298 (0.00%) 0 | 0 / 298 (0.00%) 0 |
| Reproductive system and breast disorders | | | |
| Vulvovaginal discomfort subjects affected / exposed occurrences (all) | 0 / 294 (0.00%) 0 | 0 / 298 (0.00%) 0 | 0 / 298 (0.00%) 0 |
| Penile adhesion subjects affected / exposed occurrences (all) | 0 / 294 (0.00%) 0 | 0 / 298 (0.00%) 0 | 0 / 298 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough subjects affected / exposed occurrences (all) | 0 / 294 (0.00%) 0 | 5 / 298 (1.68%) 5 | 0 / 298 (0.00%) 0 |
| Rhinorrhoea subjects affected / exposed occurrences (all) | 0 / 294 (0.00%) 0 | 0 / 298 (0.00%) 0 | 0 / 298 (0.00%) 0 |
| Epistaxis subjects affected / exposed occurrences (all) | 0 / 294 (0.00%) 0 | 0 / 298 (0.00%) 0 | 0 / 298 (0.00%) 0 |
| Nasal congestion subjects affected / exposed occurrences (all) | 0 / 294 (0.00%) 0 | 1 / 298 (0.34%) 1 | 0 / 298 (0.00%) 0 |
| Pneumonitis subjects affected / exposed occurrences (all) | 0 / 294 (0.00%) 0 | 0 / 298 (0.00%) 0 | 0 / 298 (0.00%) 0 |
| Sinus congestion subjects affected / exposed occurrences (all) | 0 / 294 (0.00%) 0 | 0 / 298 (0.00%) 0 | 0 / 298 (0.00%) 0 |
| Wheezing subjects affected / exposed occurrences (all) | 0 / 294 (0.00%) 0 | 0 / 298 (0.00%) 0 | 0 / 298 (0.00%) 0 |
| Asthma | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 2 / 294 (0.68%) | 2 / 298 (0.67%) | 0 / 298 (0.00%) |
| occurrences (all) | 2 | 2 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 5 / 298 (1.68%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 5 | 0 |
| Rhinitis allergic | | | |
| subjects affected / exposed | 1 / 294 (0.34%) | 0 / 298 (0.00%) | 1 / 298 (0.34%) |
| occurrences (all) | 1 | 0 | 1 |
| Bronchospasm | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Interstitial lung disease | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 2 / 294 (0.68%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Paranasal sinus hypersecretion | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sneezing | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Breath holding | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sleep disorder | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Asperger's disorder | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Attention deficit/hyperactivity disorder | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 294 (0.00%) 0 | 0 / 298 (0.00%) 0 | 0 / 298 (0.00%) 0 |
| Anxiety subjects affected / exposed occurrences (all) | 0 / 294 (0.00%) 0 | 1 / 298 (0.34%) 1 | 0 / 298 (0.00%) 0 |
| Depression subjects affected / exposed occurrences (all) | 0 / 294 (0.00%) 0 | 1 / 298 (0.34%) 1 | 1 / 298 (0.34%) 1 |
| Investigations Cardiac murmur subjects affected / exposed occurrences (all) | 0 / 294 (0.00%) 0 | 0 / 298 (0.00%) 0 | 0 / 298 (0.00%) 0 |
| Heart rate decreased subjects affected / exposed occurrences (all) | 0 / 294 (0.00%) 0 | 1 / 298 (0.34%) 1 | 0 / 298 (0.00%) 0 |
| Injury, poisoning and procedural complications Skin laceration subjects affected / exposed occurrences (all) | 0 / 294 (0.00%) 0 | 0 / 298 (0.00%) 0 | 0 / 298 (0.00%) 0 |
| Excoriation subjects affected / exposed occurrences (all) | 0 / 294 (0.00%) 0 | 0 / 298 (0.00%) 0 | 0 / 298 (0.00%) 0 |
| Lower limb fracture subjects affected / exposed occurrences (all) | 0 / 294 (0.00%) 0 | 0 / 298 (0.00%) 0 | 0 / 298 (0.00%) 0 |
| Head injury subjects affected / exposed occurrences (all) | 0 / 294 (0.00%) 0 | 1 / 298 (0.34%) 1 | 0 / 298 (0.00%) 0 |
| Laceration subjects affected / exposed occurrences (all) | 0 / 294 (0.00%) 0 | 0 / 298 (0.00%) 0 | 0 / 298 (0.00%) 0 |
| Mouth injury subjects affected / exposed occurrences (all) | 0 / 294 (0.00%) 0 | 0 / 298 (0.00%) 0 | 0 / 298 (0.00%) 0 |
| Burns second degree | | | |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Traumatic brain injury | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ulna fracture | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye injury | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand fracture | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 2 / 298 (0.67%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Periorbital haematoma | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 1 / 298 (0.34%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Foot fracture | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 1 / 298 (0.34%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Limb injury | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 1 / 298 (0.34%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Muscle strain | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 1 / 298 (0.34%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 1 / 298 (0.34%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Wrist fracture | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 294 (0.00%) 0 | 1 / 298 (0.34%) 1 | 0 / 298 (0.00%) 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 10 / 298 (3.36%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 11 | 0 |
| Speech disorder developmental | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Presyncope | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 1 / 298 (0.34%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dizziness | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 2 / 298 (0.67%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Migraine | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 1 / 298 (0.34%) | 1 / 298 (0.34%) |
| occurrences (all) | 0 | 1 | 1 |
| Somnolence | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 1 / 298 (0.34%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Leukocytosis | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear and labyrinth disorders | | | |
| Ear pain | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eustachian tube dysfunction | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 294 (0.00%) 0 | 1 / 298 (0.34%) 1 | 0 / 298 (0.00%) 0 |
| Eye disorders | | | |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypermetropia | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye swelling | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lacrimation increased | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myopia | | | |
| subjects affected / exposed | 1 / 294 (0.34%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Vomiting | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 4 / 298 (1.34%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 1 / 298 (0.34%) | 1 / 298 (0.34%) |
| occurrences (all) | 0 | 1 | 1 |
| Constipation | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 1 / 298 (0.34%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Tongue coated | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Duodenogastric reflux | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 294 (0.00%) | 1 / 298 (0.34%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Lip dry | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Teething | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 1 / 298 (0.34%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 3 / 298 (1.01%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Irritable bowel syndrome | | | |
| subjects affected / exposed | 1 / 294 (0.34%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Toothache | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 1 / 298 (0.34%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Uvulitis | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 1 / 298 (0.34%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Rash | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 1 / 298 (0.34%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dermatitis | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis contact | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis diaper | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|--|--------------------|-----------------|
| Eczema | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin disorder | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis atopic | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ingrowing nail | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acne | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 2 / 298 (0.67%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Acanthosis nigricans | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 1 / 298 (0.34%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Tenderness (any) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[9] | 0 / 294 (0.00%) | 252 / 283 (89.05%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 252 | 0 |
| Tenderness (significant) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[10] | 0 / 294 (0.00%) | 106 / 242 (43.80%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 106 | 0 |
| Swelling (any) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |

| | | | |
|---|--|-------------------------|----------------------|
| alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[11] occurrences (all) | 0 / 294 (0.00%) 0 | 86 / 233 (36.91%) 86 | 0 / 298 (0.00%) 0 |
| Swelling (mild) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[12] occurrences (all) | 0 / 294 (0.00%) 0 | 50 / 221 (22.62%) 50 | 0 / 298 (0.00%) 0 |
| Swelling (moderate) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[13] occurrences (all) | 0 / 294 (0.00%) 0 | 48 / 226 (21.24%) 48 | 0 / 298 (0.00%) 0 |
| Swelling (severe) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[14] occurrences (all) | 0 / 294 (0.00%) 0 | 4 / 214 (1.87%) 4 | 0 / 298 (0.00%) 0 |
| Redness (any) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[15] occurrences (all) | 0 / 294 (0.00%) 0 | 70 / 232 (30.17%) 70 | 0 / 298 (0.00%) 0 |
| Redness (mild) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic | | | |

| | | | |
|--|--|-------------------|-----------------|
| subjects affected / exposed ^[16] | 0 / 294 (0.00%) | 48 / 226 (21.24%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 48 | 0 |
| Redness (moderate) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[17] | 0 / 294 (0.00%) | 31 / 221 (14.03%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 31 | 0 |
| Redness (severe) | Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[18] | 0 / 294 (0.00%) | 4 / 213 (1.88%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| Renal and urinary disorders | | | |
| Dysuria | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematuria | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Back pain | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 2 / 298 (0.67%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Torticollis | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal chest pain | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 294 (0.00%) 0 | 1 / 298 (0.34%) 1 | 0 / 298 (0.00%) 0 |
| Infections and infestations | | | |
| Otitis media | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 2 / 298 (0.67%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 3 / 298 (1.01%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 3 / 298 (1.01%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 5 / 298 (1.68%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 5 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 1 / 298 (0.34%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 4 / 298 (1.34%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| Croup infectious | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 1 / 298 (0.34%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 5 / 298 (1.68%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 5 | 0 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 1 / 298 (0.34%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye infection | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Impetigo | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 5 / 298 (1.68%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 5 | 0 |
| Lice infestation | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media chronic | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia viral | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 1 / 298 (0.34%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---------------------------------------|-----------------|-----------------|-----------------|
| Skin infection | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cellulitis streptococcal | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Coxsackie viral infection | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis infected | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngitis streptococcal | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Viral rash | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intertrigo candida | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urethritis | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis externa | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 2 / 298 (0.67%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |

| | | | |
|------------------------------------|-----------------|-----------------|-----------------|
| Erythema infectiosum | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Folliculitis | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand-foot-and-mouth disease | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral herpes | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acarodermatitis | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatophytosis | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Viral pharyngitis | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acute sinusitis | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 1 / 298 (0.34%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Furuncle | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 1 / 298 (0.34%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Metabolism and nutrition disorders | | | |
| Anorexia | | | |
| subjects affected / exposed | 0 / 294 (0.00%) | 0 / 298 (0.00%) | 0 / 298 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lactose intolerance | | | |

for all days.

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

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

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

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

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

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|--------------|---|
| 19 June 2009 | 1- The sample size was increased to 300 subjects in each group to enhance the immunogenicity and safety assessments. 2- An OPA analysis on a subset of subjects in groups 3 and 4 was added. 3- The total volume of blood collected was increased to 10 mL. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported