



## Clinical trial results:

### A Phase 3, Randomized, Double-blind Trial Evaluating the Safety, Tolerability, and Immunogenicity of a 13-valent Pneumococcal Conjugate Vaccine Manufactured With and Without Polysorbate 80 in Healthy Infants Given in a 2-, 3-, 4-, and 12-Month Schedule With Routine Pediatric Vaccinations

#### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2006-001685-16 |
| Trial protocol           | Outside EU/EEA |
| Global end of trial date | 04 June 2008   |

#### Results information

|                                |              |
|--------------------------------|--------------|
| Result version number          | v1 (current) |
| This version publication date  | 29 June 2016 |
| First version publication date | 31 July 2015 |

#### Trial information

##### Trial identification

|                       |            |
|-----------------------|------------|
| Sponsor protocol code | 6096A1-009 |
|-----------------------|------------|

##### Additional study identifiers

|                                    |                 |
|------------------------------------|-----------------|
| ISRCTN number                      | -               |
| ClinicalTrials.gov id (NCT number) | NCT00366548     |
| WHO universal trial number (UTN)   | -               |
| Other trial identifiers            | Alias: B1851092 |

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 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com |
| Scientific contact           | Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com |

Notes:

##### Paediatric regulatory details

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

Notes:

## Results analysis stage

|                                                      |                   |
|------------------------------------------------------|-------------------|
| Analysis stage                                       | Final             |
| Date of interim/final analysis                       | 04 September 2008 |
| Is this the analysis of the primary completion data? | No                |
| Global end of trial reached?                         | Yes               |
| Global end of trial date                             | 04 June 2008      |
| Was the trial ended prematurely?                     | No                |

Notes:

## General information about the trial

Main objective of the trial:

1) To demonstrate that the immune responses to the 13 common pneumococcal conjugates (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) induced by 13-valent pneumococcal conjugate vaccine (13vPnC) with polysorbate 80 (13vPnC+P80) were noninferior to the immune responses induced by 13vPnC without polysorbate 80 (13vPnC-P80) when measured 1 month after the infant series. 2) The safety objective of this study was to evaluate the acceptability of the safety profile of the 13vPnC+P80 and 13vPnC-P80, as measured by the incidence rates of local (injection site) reactions, systemic events, and adverse events (AEs).

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                          | 14 November 2006 |
| 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 | Poland: 500 |
| Worldwide total number of subjects   | 500         |
| EEA total number of subjects         | 500         |

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) | 500 |
| Children (2-11 years)                    | 0   |
| Adolescents (12-17 years)                | 0   |
| Adults (18-64 years)                     | 0   |
| From 65 to 84 years                      | 0   |
| 85 years and over                        | 0   |

## Subject disposition

### Recruitment

Recruitment details:

Subjects were recruited in Poland from November 2006 to December 2006.

### Pre-assignment

Screening details:

Subjects were enrolled into the study according to inclusion or exclusion criteria without a screening period.

### Period 1

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

### Arms

|                              |                                              |
|------------------------------|----------------------------------------------|
| Are arms mutually exclusive? | Yes                                          |
| <b>Arm title</b>             | 13vPnC with (+) Polysorbate 80 Infant Series |

Arm description:

Subjects received 13vPnC with (+) P80 coadministered with combination vaccine containing diphtheria, tetanus, acellular pertussis, inactivated poliovirus, and conjugated Hib antigens (Pentaxim) and hepatitis B recombinant vaccine adsorbed (Engerix-B) at approximately 2 months of age, Pentaxim at approximately 3 months and 4 months of age.

|                                        |                   |
|----------------------------------------|-------------------|
| Arm type                               | Experimental      |
| Investigational medicinal product name | 13vPnC + P80      |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

Dosage and administration details:

Subjects received one single 0.5 milliliter (mL) dose of 13vPnC with P80 at approximately 2, 3 and 4 months of age.

|                                        |                   |
|----------------------------------------|-------------------|
| Investigational medicinal product name | Pentaxim          |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

Dosage and administration details:

Subjects received one single 0.5 mL dose of combination vaccine containing diphtheria, tetanus, acellular pertussis, inactivated poliovirus, and conjugated Hib antigens (Pentaxim) at 2, 3 and 4 months of age.

|                                        |                   |
|----------------------------------------|-------------------|
| Investigational medicinal product name | Engerix B         |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

Dosage and administration details:

Subjects received one single 0.5 mL dose of hepatitis B recombinant vaccine adsorbed (Engerix-B) at approximately 2 months of age.

|                  |                                                 |
|------------------|-------------------------------------------------|
| <b>Arm title</b> | 13vPnC without (-) Polysorbate 80 Infant Series |
|------------------|-------------------------------------------------|

**Arm description:**

Subjects received of 13vPnC without (-) P80 coadministered with combination vaccine containing diphtheria, tetanus, acellular pertussis, inactivated poliovirus, and conjugated Hib antigens (Pentaxim) and hepatitis B recombinant vaccine adsorbed (Engerix-B) at approximately 2 months of age, Pentaxim at approximately 3 months and 4 months of age.

|                                        |                   |
|----------------------------------------|-------------------|
| Arm type                               | Active comparator |
| Investigational medicinal product name | 13vPnC - P80      |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

**Dosage and administration details:**

Subjects received one single 0.5 mL dose of 13vPnC without P80 at approximately 2, 3 and 4 months of age.

|                                        |                   |
|----------------------------------------|-------------------|
| Investigational medicinal product name | Pentaxim          |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

**Dosage and administration details:**

Subjects received one single 0.5 mL dose of combination vaccine containing diphtheria, tetanus, acellular pertussis, inactivated poliovirus, and conjugated Hib antigens (Pentaxim) at 2, 3 and 4 months of age.

|                                        |                   |
|----------------------------------------|-------------------|
| Investigational medicinal product name | Engerix B         |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

**Dosage and administration details:**

Subjects received one single 0.5 mL dose of hepatitis B recombinant vaccine adsorbed (Engerix-B) at approximately 2 months of age.

| <b>Number of subjects in period 1</b> | <b>13vPnC with (+)<br/>Polysorbate 80<br/>Infant Series</b> | <b>13vPnC without (-)<br/>Polysorbate 80<br/>Infant Series</b> |
|---------------------------------------|-------------------------------------------------------------|----------------------------------------------------------------|
| Started                               | 250                                                         | 250                                                            |
| Vaccinated Dose 1                     | 250                                                         | 250                                                            |
| Vaccinated Dose 3                     | 246                                                         | 247                                                            |
| Vaccinated Dose 2                     | 246                                                         | 249                                                            |
| Completed                             | 246                                                         | 245                                                            |
| Not completed                         | 4                                                           | 5                                                              |
| Consent withdrawn by subject          | 3                                                           | 1                                                              |
| Adverse Event                         | 1                                                           | 3                                                              |
| Protocol deviation                    | -                                                           | 1                                                              |

**Period 2**

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

**Arms**

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

|                  |                                             |
|------------------|---------------------------------------------|
| <b>Arm title</b> | 13vPnC + Polysorbate 80 After Infant Series |
|------------------|---------------------------------------------|

## Arm description:

Included subjects who received one single 0.5 mL dose of 13vPnC with P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months of age in infant series.

|          |                 |
|----------|-----------------|
| Arm type | No intervention |
|----------|-----------------|

No investigational medicinal product assigned in this arm

|                  |                                             |
|------------------|---------------------------------------------|
| <b>Arm title</b> | 13vPnC - Polysorbate 80 After Infant Series |
|------------------|---------------------------------------------|

## Arm description:

Included subjects who received one single 0.5 mL dose of 13vPnC without P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months of age in infant series.

|          |                 |
|----------|-----------------|
| Arm type | No intervention |
|----------|-----------------|

No investigational medicinal product assigned in this arm

| <b>Number of subjects in period 2</b> | 13vPnC + Polysorbate 80 After Infant Series | 13vPnC - Polysorbate 80 After Infant Series |
|---------------------------------------|---------------------------------------------|---------------------------------------------|
| Started                               | 246                                         | 245                                         |
| Completed                             | 240                                         | 244                                         |
| Not completed                         | 6                                           | 1                                           |
| Consent withdrawn by subject          | 3                                           | 1                                           |
| Adverse Event                         | 2                                           | -                                           |
| Lost to follow-up                     | 1                                           | -                                           |

**Period 3**

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

**Arms**

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

|                                                                                                                                                                                             |                                            |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| <b>Arm title</b>                                                                                                                                                                            | 13vPnC - Polysorbate 80 After Toddler Dose |
| Arm description:<br>Subjects received 13vPnC without P80 coadministered with Priorix at 12 months of age (toddler dose).                                                                    |                                            |
| Arm type                                                                                                                                                                                    | Active comparator                          |
| Investigational medicinal product name                                                                                                                                                      | 13vPnC - P80                               |
| Investigational medicinal product code                                                                                                                                                      |                                            |
| Other name                                                                                                                                                                                  |                                            |
| Pharmaceutical forms                                                                                                                                                                        | Injection                                  |
| Routes of administration                                                                                                                                                                    | Intramuscular use                          |
| Dosage and administration details:<br>Subjects received one single 0.5 mL dose of 13vPnC without P80 at approximately 12 months of age.                                                     |                                            |
| Investigational medicinal product name                                                                                                                                                      | Priorix                                    |
| Investigational medicinal product code                                                                                                                                                      |                                            |
| Other name                                                                                                                                                                                  |                                            |
| Pharmaceutical forms                                                                                                                                                                        | Injection                                  |
| Routes of administration                                                                                                                                                                    | Subcutaneous use                           |
| Dosage and administration details:<br>Subjects received one single 0.5 mL dose of combined vaccine containing attenuated measles, mumps, and rubella viruses (Priorix) at 12 months of age. |                                            |
| <b>Arm title</b>                                                                                                                                                                            | 13vPnC+Polysorbate 80 After Toddler Dose   |

|                                                                                                                                                                                             |                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Arm description:<br>Subjects received 13vPnC with P80 coadministered with Priorix at 12 months of age.                                                                                      |                   |
| Arm type                                                                                                                                                                                    | Experimental      |
| Investigational medicinal product name                                                                                                                                                      | 13vPnC + P80      |
| Investigational medicinal product code                                                                                                                                                      |                   |
| Other name                                                                                                                                                                                  |                   |
| Pharmaceutical forms                                                                                                                                                                        | Injection         |
| Routes of administration                                                                                                                                                                    | Intramuscular use |
| Dosage and administration details:<br>Subjects received one single 0.5 mL dose of 13vPnC with P80 at approximately 12 months of age.                                                        |                   |
| Investigational medicinal product name                                                                                                                                                      | Priorix           |
| Investigational medicinal product code                                                                                                                                                      |                   |
| Other name                                                                                                                                                                                  |                   |
| Pharmaceutical forms                                                                                                                                                                        | Injection         |
| Routes of administration                                                                                                                                                                    | Subcutaneous use  |
| Dosage and administration details:<br>Subjects received one single 0.5 mL dose of combined vaccine containing attenuated measles, mumps, and rubella viruses (Priorix) at 12 months of age. |                   |

| <b>Number of subjects in period 3</b> | 13vPnC - Polysorbate 80 After Toddler Dose | 13vPnC+Polysorbate 80 After Toddler Dose |
|---------------------------------------|--------------------------------------------|------------------------------------------|
| Started                               | 244                                        | 240                                      |
| Completed                             | 244                                        | 240                                      |



## Baseline characteristics

### Reporting groups

|                                                                                                                                                                                                                                                                                                                                                                                            |                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                      | 13vPnC with (+) Polysorbate 80 Infant Series    |
| Reporting group description:<br>Subjects received 13vPnC with (+) P80 coadministered with combination vaccine containing diphtheria, tetanus, acellular pertussis, inactivated poliovirus, and conjugated Hib antigens (Pentaxim) and hepatitis B recombinant vaccine adsorbed (Engerix-B) at approximately 2 months of age, Pentaxim at approximately 3 months and 4 months of age.       |                                                 |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                      | 13vPnC without (-) Polysorbate 80 Infant Series |
| Reporting group description:<br>Subjects received of 13vPnC without (-) P80 coadministered with combination vaccine containing diphtheria, tetanus, acellular pertussis, inactivated poliovirus, and conjugated Hib antigens (Pentaxim) and hepatitis B recombinant vaccine adsorbed (Engerix-B) at approximately 2 months of age, Pentaxim at approximately 3 months and 4 months of age. |                                                 |

| Reporting group values                                                   | 13vPnC with (+)<br>Polysorbate 80<br>Infant Series | 13vPnC without (-)<br>Polysorbate 80<br>Infant Series | Total |
|--------------------------------------------------------------------------|----------------------------------------------------|-------------------------------------------------------|-------|
| Number of subjects                                                       | 250                                                | 250                                                   | 500   |
| Age categorical<br>Units: Subjects                                       |                                                    |                                                       |       |
| Age continuous<br>Units: months<br>arithmetic mean<br>standard deviation | 2.1<br>± 0.5                                       | 2.1<br>± 0.5                                          | -     |
| Gender categorical<br>Units: Subjects                                    |                                                    |                                                       |       |
| Female                                                                   | 122                                                | 122                                                   | 244   |
| Male                                                                     | 128                                                | 128                                                   | 256   |

## End points

### End points reporting groups

|                                                                                                                                                                                                                                                                                                                                                                                            |                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                      | 13vPnC with (+) Polysorbate 80 Infant Series    |
| Reporting group description:<br>Subjects received 13vPnC with (+) P80 coadministered with combination vaccine containing diphtheria, tetanus, acellular pertussis, inactivated poliovirus, and conjugated Hib antigens (Pentaxim) and hepatitis B recombinant vaccine adsorbed (Engerix-B) at approximately 2 months of age, Pentaxim at approximately 3 months and 4 months of age.       |                                                 |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                      | 13vPnC without (-) Polysorbate 80 Infant Series |
| Reporting group description:<br>Subjects received of 13vPnC without (-) P80 coadministered with combination vaccine containing diphtheria, tetanus, acellular pertussis, inactivated poliovirus, and conjugated Hib antigens (Pentaxim) and hepatitis B recombinant vaccine adsorbed (Engerix-B) at approximately 2 months of age, Pentaxim at approximately 3 months and 4 months of age. |                                                 |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                      | 13vPnC + Polysorbate 80 After Infant Series     |
| Reporting group description:<br>Included subjects who received one single 0.5 mL dose of 13vPnC with P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months of age in infant series.                                                                                                                                                                |                                                 |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                      | 13vPnC - Polysorbate 80 After Infant Series     |
| Reporting group description:<br>Included subjects who received one single 0.5 mL dose of 13vPnC without P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months of age in infant series.                                                                                                                                                             |                                                 |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                      | 13vPnC - Polysorbate 80 After Toddler Dose      |
| Reporting group description:<br>Subjects received 13vPnC without P80 coadministered with Priorix at 12 months of age (toddler dose).                                                                                                                                                                                                                                                       |                                                 |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                      | 13vPnC+Polysorbate 80 After Toddler Dose        |
| Reporting group description:<br>Subjects received 13vPnC with P80 coadministered with Priorix at 12 months of age.                                                                                                                                                                                                                                                                         |                                                 |
| Subject analysis set title                                                                                                                                                                                                                                                                                                                                                                 | 13vPnC + P80 Dose 1 Infant Series               |
| Subject analysis set type                                                                                                                                                                                                                                                                                                                                                                  | Sub-group analysis                              |
| Subject analysis set description:<br>Subjects received one single 0.5mL dose of 13vPnC + P80 coadministered with Pentaxim and Engerix-B at 2 months of age (infant series, Dose 1).                                                                                                                                                                                                        |                                                 |
| Subject analysis set title                                                                                                                                                                                                                                                                                                                                                                 | 13vPnC - P 80 Dose 1 Infant Series              |
| Subject analysis set type                                                                                                                                                                                                                                                                                                                                                                  | Sub-group analysis                              |
| Subject analysis set description:<br>Subjects received one single 0.5mL dose of 13vPnC - P80 coadministered with Pentaxim and Engerix-B at 2 months of age (infant series, Dose 1).                                                                                                                                                                                                        |                                                 |
| Subject analysis set title                                                                                                                                                                                                                                                                                                                                                                 | 13vPnC + P80 Dose 2 Infant Series               |
| Subject analysis set type                                                                                                                                                                                                                                                                                                                                                                  | Sub-group analysis                              |
| Subject analysis set description:<br>Subjects received one single 0.5mL dose of 13vPnC + P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 months age (infant series, Dose 2).                                                                                                                                                                              |                                                 |
| Subject analysis set title                                                                                                                                                                                                                                                                                                                                                                 | 13vPnC - P80 Dose 2 Infant Series               |
| Subject analysis set type                                                                                                                                                                                                                                                                                                                                                                  | Sub-group analysis                              |
| Subject analysis set description:<br>Subjects received one single 0.5mL dose of 13vPnC - P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 months age (infant series, Dose 2).                                                                                                                                                                              |                                                 |
| Subject analysis set title                                                                                                                                                                                                                                                                                                                                                                 | 13vPnC - P80 Dose 3 Infant Series               |
| Subject analysis set type                                                                                                                                                                                                                                                                                                                                                                  | Sub-group analysis                              |
| Subject analysis set description:<br>Subjects received one single 0.5mL dose of 13vPnC - P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months age (infant series, Dose 3).                                                                                                                                                                        |                                                 |

|                                                                                                                                                                                                                        |                                   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| Subject analysis set title                                                                                                                                                                                             | 13vPnC + P80 Dose 3 Infant Series |
| Subject analysis set type                                                                                                                                                                                              | Sub-group analysis                |
| Subject analysis set description:                                                                                                                                                                                      |                                   |
| Subjects received one single 0.5mL dose of 13vPnC + P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months age (infant series, Dose 3).                                         |                                   |
| Subject analysis set title                                                                                                                                                                                             | 13vPnC + P80 Toddler Dose         |
| Subject analysis set type                                                                                                                                                                                              | Sub-group analysis                |
| Subject analysis set description:                                                                                                                                                                                      |                                   |
| Subjects received one single 0.5mL dose of 13vPnC + P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months age (infant series), and Priorix at 12 months of age (toddler dose). |                                   |
| Subject analysis set title                                                                                                                                                                                             | 13vPnC - P80 Toddler Dose         |
| Subject analysis set type                                                                                                                                                                                              | Sub-group analysis                |
| Subject analysis set description:                                                                                                                                                                                      |                                   |
| Subjects received one single 0.5mL dose of 13vPnC - P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months age (infant series), and Priorix at 12 months of age (toddler dose). |                                   |

**Primary: Percentage of Subjects Achieving Antibody Level Greater Than or Equal to ( $\geq$ ) 0.35 microgram per milliliter ( $\mu\text{g/mL}$ ) in 13vPnC+P80 Group Relative to 13vPnC-80 Group After the Infant Series**

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Percentage of Subjects Achieving Antibody Level Greater Than or Equal to ( $\geq$ ) 0.35 microgram per milliliter ( $\mu\text{g/mL}$ ) in 13vPnC+P80 Group Relative to 13vPnC-80 Group After the Infant Series |
| End point description:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                |
| Percentages of subjects achieving World Health Organization (WHO) predefined antibody threshold $\geq 0.35 \mu\text{g/mL}$ along with the corresponding 95 percent (%) 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. Evaluable immunogenicity population had valid and determinate assay results, and had no other major protocol violations, (n) = number of subjects with an antibody concentration $\geq 0.35$ micro gram per milliliter ( $\text{mcg/mL}$ ) for the given serotype. |                                                                                                                                                                                                                |
| End point type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Primary                                                                                                                                                                                                        |
| End point timeframe:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                |
| One month after 3-dose infant series (at 5 months of age)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                |

| End point values                            | 13vPnC - Polysorbate 80 After Infant Series | 13vPnC + Polysorbate 80 After Infant Series |  |  |
|---------------------------------------------|---------------------------------------------|---------------------------------------------|--|--|
| Subject group type                          | Reporting group                             | Reporting group                             |  |  |
| Number of subjects analysed                 | 238 <sup>[1]</sup>                          | 238 <sup>[2]</sup>                          |  |  |
| Units: percentage of subjects               |                                             |                                             |  |  |
| number (confidence interval 95%)            |                                             |                                             |  |  |
| Common Serotypes - Serotype 4 (n=222,224)   | 94.1 (90.3 to 96.7)                         | 93.3 (89.3 to 96.1)                         |  |  |
| Common Serotypes - Serotype 6B (n=145,158)  | 66.4 (60 to 72.4)                           | 60.9 (54.4 to 67.2)                         |  |  |
| Common Serotypes - Serotype 9V (n=231,232)  | 97.5 (94.6 to 99.1)                         | 97.1 (94 to 98.8)                           |  |  |
| Common Serotypes - Serotype 14 (n=225,232)  | 97.5 (94.6 to 99.1)                         | 94.5 (90.8 to 97.1)                         |  |  |
| Common Serotypes - Serotype 18C (n=233,233) | 97.9 (95.2 to 99.3)                         | 97.9 (95.2 to 99.3)                         |  |  |

|                                                 |                     |                     |  |  |
|-------------------------------------------------|---------------------|---------------------|--|--|
| Common Serotypes - Serotype 19F (n=228,234)     | 98.3 (95.8 to 99.5) | 95.8 (92.4 to 98)   |  |  |
| Common Serotypes - Serotype 23F (n=205,220)     | 92.4 (88.3 to 95.5) | 86.1 (81.1 to 90.3) |  |  |
| Additional Serotypes - Serotype 1 (n=228,220)   | 92.4 (88.3 to 95.5) | 95.8 (92.4 to 98)   |  |  |
| Additional Serotypes - Serotype 3 (n=233,236)   | 99.2 (97 to 99.9)   | 97.9 (95.2 to 99.3) |  |  |
| Additional Serotypes - Serotype 5 (n=224,220)   | 92.4 (88.3 to 95.5) | 94.1 (90.3 to 96.7) |  |  |
| Additional Serotypes - Serotype 6A (n=206,205)  | 86.1 (81.1 to 90.3) | 86.6 (81.6 to 90.6) |  |  |
| Additional Serotypes - Serotype 7F (n=235,237)  | 99.6 (97.7 to 100)  | 98.7 (96.4 to 99.7) |  |  |
| Additional Serotypes - Serotype 19A (n=235,238) | 100 (98.5 to 100)   | 98.7 (96.4 to 99.7) |  |  |

Notes:

[1] - Subjects with a determinate antibody concentration for the specified serotype.

[2] - Subjects with a determinate antibody concentration for the specified serotype.

## Statistical analyses

| Statistical analysis title                                                                 | Serotype 4                                                                                |
|--------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| Statistical analysis description:                                                          |                                                                                           |
| Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated. |                                                                                           |
| Comparison groups                                                                          | 13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series |
| Number of subjects included in analysis                                                    | 476                                                                                       |
| Analysis specification                                                                     | Pre-specified                                                                             |
| Analysis type                                                                              | non-inferiority <sup>[3]</sup>                                                            |
| Parameter estimate                                                                         | Difference in percentage                                                                  |
| Point estimate                                                                             | -0.8                                                                                      |
| Confidence interval                                                                        |                                                                                           |
| level                                                                                      | 95 %                                                                                      |
| sides                                                                                      | 2-sided                                                                                   |
| lower limit                                                                                | -5.4                                                                                      |
| upper limit                                                                                | 3.7                                                                                       |

Notes:

[3] - Non-inferiority for each common serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups greater than (>) -10%.

| Statistical analysis title                                                                 | Serotype 6B                                                                               |
|--------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| Statistical analysis description:                                                          |                                                                                           |
| Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated. |                                                                                           |
| Comparison groups                                                                          | 13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series |
| Number of subjects included in analysis                                                    | 476                                                                                       |
| Analysis specification                                                                     | Pre-specified                                                                             |
| Analysis type                                                                              | non-inferiority <sup>[4]</sup>                                                            |
| Parameter estimate                                                                         | Difference in percentage                                                                  |
| Point estimate                                                                             | -5.5                                                                                      |
| Confidence interval                                                                        |                                                                                           |
| level                                                                                      | 95 %                                                                                      |
| sides                                                                                      | 2-sided                                                                                   |
| lower limit                                                                                | -14.2                                                                                     |
| upper limit                                                                                | 3.3                                                                                       |

Notes:

[4] - Non-inferiority for each common serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

| Statistical analysis title                                                                 | Serotype 9V                                                                               |
|--------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| Statistical analysis description:                                                          |                                                                                           |
| Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated. |                                                                                           |
| Comparison groups                                                                          | 13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series |
| Number of subjects included in analysis                                                    | 476                                                                                       |
| Analysis specification                                                                     | Pre-specified                                                                             |
| Analysis type                                                                              | non-inferiority <sup>[5]</sup>                                                            |
| Parameter estimate                                                                         | Difference in percentage                                                                  |
| Point estimate                                                                             | -0.4                                                                                      |
| Confidence interval                                                                        |                                                                                           |
| level                                                                                      | 95 %                                                                                      |
| sides                                                                                      | 2-sided                                                                                   |
| lower limit                                                                                | -3.7                                                                                      |
| upper limit                                                                                | 2.8                                                                                       |

Notes:

[5] - Non-inferiority for each common serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

| Statistical analysis title                                                                 | Serotype 14                                                                               |
|--------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| Statistical analysis description:                                                          |                                                                                           |
| Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated. |                                                                                           |
| Comparison groups                                                                          | 13vPnC - Polysorbate 80 After Infant Series v 13vPnC + Polysorbate 80 After Infant Series |
| Number of subjects included in analysis                                                    | 476                                                                                       |
| Analysis specification                                                                     | Pre-specified                                                                             |
| Analysis type                                                                              | non-inferiority <sup>[6]</sup>                                                            |
| Parameter estimate                                                                         | Difference in percentage                                                                  |
| Point estimate                                                                             | -2.9                                                                                      |
| Confidence interval                                                                        |                                                                                           |
| level                                                                                      | 95 %                                                                                      |
| sides                                                                                      | 2-sided                                                                                   |
| lower limit                                                                                | -6.9                                                                                      |
| upper limit                                                                                | 0.7                                                                                       |

Notes:

[6] - Non-inferiority for each common serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

| Statistical analysis title                                                                 | Serotype 18C                                                                              |
|--------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| Statistical analysis description:                                                          |                                                                                           |
| Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated. |                                                                                           |
| Comparison groups                                                                          | 13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series |
| Number of subjects included in analysis                                                    | 476                                                                                       |
| Analysis specification                                                                     | Pre-specified                                                                             |
| Analysis type                                                                              | non-inferiority <sup>[7]</sup>                                                            |
| Parameter estimate                                                                         | Difference in percentage                                                                  |
| Point estimate                                                                             | 0                                                                                         |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | -3      |
| upper limit         | 3       |

Notes:

[7] - Non-inferiority for each common serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

|                                   |              |
|-----------------------------------|--------------|
| <b>Statistical analysis title</b> | Serotype 19F |
|-----------------------------------|--------------|

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

|                                         |                                                                                           |
|-----------------------------------------|-------------------------------------------------------------------------------------------|
| Comparison groups                       | 13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series |
| Number of subjects included in analysis | 476                                                                                       |
| Analysis specification                  | Pre-specified                                                                             |
| Analysis type                           | non-inferiority <sup>[8]</sup>                                                            |
| Parameter estimate                      | Difference in percentage                                                                  |
| Point estimate                          | -2.5                                                                                      |

Confidence interval

|             |         |
|-------------|---------|
| level       | 95 %    |
| sides       | 2-sided |
| lower limit | -6.1    |
| upper limit | 0.6     |

Notes:

[8] - Non-inferiority for each common serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

|                                   |              |
|-----------------------------------|--------------|
| <b>Statistical analysis title</b> | Serotype 23F |
|-----------------------------------|--------------|

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

|                                         |                                                                                           |
|-----------------------------------------|-------------------------------------------------------------------------------------------|
| Comparison groups                       | 13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series |
| Number of subjects included in analysis | 476                                                                                       |
| Analysis specification                  | Pre-specified                                                                             |
| Analysis type                           | non-inferiority <sup>[9]</sup>                                                            |
| Parameter estimate                      | Difference in percentage                                                                  |
| Point estimate                          | -6.3                                                                                      |

Confidence interval

|             |         |
|-------------|---------|
| level       | 95 %    |
| sides       | 2-sided |
| lower limit | -12.1   |
| upper limit | -0.7    |

Notes:

[9] - Non-inferiority for each common serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

|                                   |            |
|-----------------------------------|------------|
| <b>Statistical analysis title</b> | Serotype 1 |
|-----------------------------------|------------|

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

|                   |                                                                                           |
|-------------------|-------------------------------------------------------------------------------------------|
| Comparison groups | 13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series |
|-------------------|-------------------------------------------------------------------------------------------|

|                                         |                                 |
|-----------------------------------------|---------------------------------|
| Number of subjects included in analysis | 476                             |
| Analysis specification                  | Pre-specified                   |
| Analysis type                           | non-inferiority <sup>[10]</sup> |
| Parameter estimate                      | Difference in percentage        |
| Point estimate                          | 3.4                             |
| Confidence interval                     |                                 |
| level                                   | 95 %                            |
| sides                                   | 2-sided                         |
| lower limit                             | -0.9                            |
| upper limit                             | 7.9                             |

Notes:

[10] - Non-inferiority for each additional serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

|                                   |            |
|-----------------------------------|------------|
| <b>Statistical analysis title</b> | Serotype 3 |
|-----------------------------------|------------|

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

|                                         |                                                                                           |
|-----------------------------------------|-------------------------------------------------------------------------------------------|
| Comparison groups                       | 13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series |
| Number of subjects included in analysis | 476                                                                                       |
| Analysis specification                  | Pre-specified                                                                             |
| Analysis type                           | non-inferiority <sup>[11]</sup>                                                           |
| Parameter estimate                      | Difference in percentage                                                                  |
| Point estimate                          | -1.3                                                                                      |
| Confidence interval                     |                                                                                           |
| level                                   | 95 %                                                                                      |
| sides                                   | 2-sided                                                                                   |
| lower limit                             | -4.1                                                                                      |
| upper limit                             | 1.1                                                                                       |

Notes:

[11] - Non-inferiority for each additional serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

|                                   |            |
|-----------------------------------|------------|
| <b>Statistical analysis title</b> | Serotype 5 |
|-----------------------------------|------------|

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

|                                         |                                                                                           |
|-----------------------------------------|-------------------------------------------------------------------------------------------|
| Comparison groups                       | 13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series |
| Number of subjects included in analysis | 476                                                                                       |
| Analysis specification                  | Pre-specified                                                                             |
| Analysis type                           | non-inferiority <sup>[12]</sup>                                                           |
| Parameter estimate                      | Difference in percentage                                                                  |
| Point estimate                          | 1.7                                                                                       |
| Confidence interval                     |                                                                                           |
| level                                   | 95 %                                                                                      |
| sides                                   | 2-sided                                                                                   |
| lower limit                             | -3                                                                                        |
| upper limit                             | 6.4                                                                                       |

Notes:

[12] - Non-inferiority for each additional serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

|                                   |             |
|-----------------------------------|-------------|
| <b>Statistical analysis title</b> | Serotype 6A |
|-----------------------------------|-------------|

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

|                                         |                                                                                           |
|-----------------------------------------|-------------------------------------------------------------------------------------------|
| Comparison groups                       | 13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series |
| Number of subjects included in analysis | 476                                                                                       |
| Analysis specification                  | Pre-specified                                                                             |
| Analysis type                           | non-inferiority <sup>[13]</sup>                                                           |
| Parameter estimate                      | Difference in percentage                                                                  |
| Point estimate                          | 0.4                                                                                       |
| Confidence interval                     |                                                                                           |
| level                                   | 95 %                                                                                      |
| sides                                   | 2-sided                                                                                   |
| lower limit                             | -5.8                                                                                      |
| upper limit                             | 6.7                                                                                       |

Notes:

[13] - Non-inferiority for each additional serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

|                                   |             |
|-----------------------------------|-------------|
| <b>Statistical analysis title</b> | Serotype 7F |
|-----------------------------------|-------------|

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

|                                         |                                                                                           |
|-----------------------------------------|-------------------------------------------------------------------------------------------|
| Comparison groups                       | 13vPnC - Polysorbate 80 After Infant Series v 13vPnC + Polysorbate 80 After Infant Series |
| Number of subjects included in analysis | 476                                                                                       |
| Analysis specification                  | Pre-specified                                                                             |
| Analysis type                           | non-inferiority <sup>[14]</sup>                                                           |
| Parameter estimate                      | Difference in percentage                                                                  |
| Point estimate                          | -0.8                                                                                      |
| Confidence interval                     |                                                                                           |
| level                                   | 95 %                                                                                      |
| sides                                   | 2-sided                                                                                   |
| lower limit                             | -3.2                                                                                      |
| upper limit                             | 1.2                                                                                       |

Notes:

[14] - Non-inferiority for each additional serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

|                                   |              |
|-----------------------------------|--------------|
| <b>Statistical analysis title</b> | Serotype 19A |
|-----------------------------------|--------------|

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

|                                         |                                                                                           |
|-----------------------------------------|-------------------------------------------------------------------------------------------|
| Comparison groups                       | 13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series |
| Number of subjects included in analysis | 476                                                                                       |
| Analysis specification                  | Pre-specified                                                                             |
| Analysis type                           | non-inferiority <sup>[15]</sup>                                                           |
| Parameter estimate                      | Difference in percentage                                                                  |
| Point estimate                          | -1.3                                                                                      |
| Confidence interval                     |                                                                                           |
| level                                   | 95 %                                                                                      |
| sides                                   | 2-sided                                                                                   |
| lower limit                             | -3.6                                                                                      |
| upper limit                             | 0.3                                                                                       |

Notes:

[15] - Non-inferiority for each additional serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

**Primary: Geometric Mean Antibody Concentration (GMC) in 13vPnC+P80 Group Relative to 13vPnC-P80 Group After the 3-Dose Infant Series**

|                 |                                                                                                                             |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------|
| End point title | Geometric Mean Antibody Concentration (GMC) in 13vPnC+P80 Group Relative to 13vPnC-P80 Group After the 3-Dose Infant Series |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------|

End point description:

GMC as measured by enzyme-linked immunosorbent assay (ELISA) for 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. Evaluable immunogenicity population had valid and determinate assay results, and had no other major protocol violations.

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

End point timeframe:

1 month after 3-dose infant series (at 5 months of age)

| End point values                         | 13vPnC - Polysorbate 80 After Infant Series | 13vPnC + Polysorbate 80 After Infant Series |  |  |
|------------------------------------------|---------------------------------------------|---------------------------------------------|--|--|
| Subject group type                       | Reporting group                             | Reporting group                             |  |  |
| Number of subjects analysed              | 238 <sup>[16]</sup>                         | 238 <sup>[17]</sup>                         |  |  |
| Units: µg/mL                             |                                             |                                             |  |  |
| geometric mean (confidence interval 95%) |                                             |                                             |  |  |
| Common Serotypes - Serotype 4            | 1.53 (1.36 to 1.72)                         | 1.47 (1.3 to 1.65)                          |  |  |
| Common Serotypes - Serotype 6B           | 0.57 (0.48 to 0.68)                         | 0.51 (0.44 to 0.6)                          |  |  |
| Common Serotypes - Serotype 9V           | 1.51 (1.38 to 1.65)                         | 1.46 (1.34 to 1.6)                          |  |  |
| Common Serotypes - Serotype 14           | 2.48 (2.2 to 2.8)                           | 2.37 (2.06 to 2.73)                         |  |  |
| Common Serotypes - Serotype 18C          | 1.87 (1.71 to 2.04)                         | 1.84 (1.67 to 2.03)                         |  |  |
| Common Serotypes - Serotype 19F          | 1.75 (1.6 to 1.91)                          | 1.46 (1.3 to 1.65)                          |  |  |
| Common Serotypes - Serotype 23F          | 1.11 (1 to 1.24)                            | 0.93 (0.83 to 1.05)                         |  |  |
| Additional Serotypes - Serotype 1        | 1.48 (1.32 to 1.66)                         | 1.39 (1.26 to 1.55)                         |  |  |
| Additional Serotypes - Serotype 3        | 1.62 (1.49 to 1.75)                         | 1.5 (1.38 to 1.63)                          |  |  |
| Additional Serotypes - Serotype 5        | 1.3 (1.16 to 1.44)                          | 1.26 (1.13 to 1.4)                          |  |  |
| Additional Serotypes - Serotype 6A       | 1.04 (0.92 to 1.17)                         | 0.99 (0.88 to 1.12)                         |  |  |
| Additional Serotypes - Serotype 7F       | 1.89 (1.73 to 2.06)                         | 1.98 (1.81 to 2.15)                         |  |  |
| Additional Serotypes - Serotype 19A      | 2.94 (2.69 to 3.21)                         | 2.68 (2.44 to 2.95)                         |  |  |

Notes:

[16] - Subjects with a determinate IgG antibody concentration to the specified serotype.

## Statistical analyses

|                                                                                        |                                                                                           |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| <b>Statistical analysis title</b>                                                      | Serotype 4                                                                                |
| Statistical analysis description:<br>GMC ratio (13vPnC+P80/13vPnC-P80) was calculated. |                                                                                           |
| Comparison groups                                                                      | 13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series |
| Number of subjects included in analysis                                                | 476                                                                                       |
| Analysis specification                                                                 | Pre-specified                                                                             |
| Analysis type                                                                          | non-inferiority <sup>[18]</sup>                                                           |
| Parameter estimate                                                                     | GMC ratio                                                                                 |
| Point estimate                                                                         | 0.96                                                                                      |
| Confidence interval                                                                    |                                                                                           |
| level                                                                                  | 95 %                                                                                      |
| sides                                                                                  | 2-sided                                                                                   |
| lower limit                                                                            | 0.81                                                                                      |
| upper limit                                                                            | 1.13                                                                                      |

Notes:

[18] - Non-inferiority for each common serotype was declared if the lower limit of the 2-sided 95% CI for the GMC ratio (13vPnC+P80/13vPnC-P80) > 0.5 (2-fold criterion).

|                                                                                        |                                                                                           |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| <b>Statistical analysis title</b>                                                      | Serotype 9V                                                                               |
| Statistical analysis description:<br>GMC ratio (13vPnC+P80/13vPnC-P80) was calculated. |                                                                                           |
| Comparison groups                                                                      | 13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series |
| Number of subjects included in analysis                                                | 476                                                                                       |
| Analysis specification                                                                 | Pre-specified                                                                             |
| Analysis type                                                                          | non-inferiority <sup>[19]</sup>                                                           |
| Parameter estimate                                                                     | GMC ratio                                                                                 |
| Point estimate                                                                         | 0.97                                                                                      |
| Confidence interval                                                                    |                                                                                           |
| level                                                                                  | 95 %                                                                                      |
| sides                                                                                  | 2-sided                                                                                   |
| lower limit                                                                            | 0.85                                                                                      |
| upper limit                                                                            | 1.1                                                                                       |

Notes:

[19] - Non-inferiority for each common serotype was declared if the lower limit of the 2-sided 95% CI for the GMC ratio (13vPnC+P80/13vPnC-P80) > 0.5 (2-fold criterion).

|                                                                                        |                                                                                           |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| <b>Statistical analysis title</b>                                                      | Serotype 6B                                                                               |
| Statistical analysis description:<br>GMC ratio (13vPnC+P80/13vPnC-P80) was calculated. |                                                                                           |
| Comparison groups                                                                      | 13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series |

|                                         |                                 |
|-----------------------------------------|---------------------------------|
| Number of subjects included in analysis | 476                             |
| Analysis specification                  | Pre-specified                   |
| Analysis type                           | non-inferiority <sup>[20]</sup> |
| Parameter estimate                      | GMC ratio                       |
| Point estimate                          | 0.9                             |
| Confidence interval                     |                                 |
| level                                   | 95 %                            |
| sides                                   | 2-sided                         |
| lower limit                             | 0.72                            |
| upper limit                             | 1.14                            |

Notes:

[20] - Non-inferiority for each common serotype was declared if the lower limit of the 2-sided 95% CI for the GMC ratio (13vPnC+P80/13vPnC-P80) > 0.5 (2-fold criterion).

|                                                   |                                                                                           |
|---------------------------------------------------|-------------------------------------------------------------------------------------------|
| <b>Statistical analysis title</b>                 | Serotype 14                                                                               |
| Statistical analysis description:                 |                                                                                           |
| GMC ratio (13vPnC+P80/13vPnC-P80) was calculated. |                                                                                           |
| Comparison groups                                 | 13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series |
| Number of subjects included in analysis           | 476                                                                                       |
| Analysis specification                            | Pre-specified                                                                             |
| Analysis type                                     | non-inferiority <sup>[21]</sup>                                                           |
| Parameter estimate                                | GMC ratio                                                                                 |
| Point estimate                                    | 0.96                                                                                      |
| Confidence interval                               |                                                                                           |
| level                                             | 95 %                                                                                      |
| sides                                             | 2-sided                                                                                   |
| lower limit                                       | 0.79                                                                                      |
| upper limit                                       | 1.15                                                                                      |

Notes:

[21] - Non-inferiority for each common serotype was declared if the lower limit of the 2-sided 95% CI for the GMC ratio (13vPnC+P80/13vPnC-P80) > 0.5 (2-fold criterion).

|                                                   |                                                                                           |
|---------------------------------------------------|-------------------------------------------------------------------------------------------|
| <b>Statistical analysis title</b>                 | Serotype 18C                                                                              |
| Statistical analysis description:                 |                                                                                           |
| GMC ratio (13vPnC+P80/13vPnC-P80) was calculated. |                                                                                           |
| Comparison groups                                 | 13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series |
| Number of subjects included in analysis           | 476                                                                                       |
| Analysis specification                            | Pre-specified                                                                             |
| Analysis type                                     | non-inferiority <sup>[22]</sup>                                                           |
| Parameter estimate                                | GMC ratio                                                                                 |
| Point estimate                                    | 0.98                                                                                      |
| Confidence interval                               |                                                                                           |
| level                                             | 95 %                                                                                      |
| sides                                             | 2-sided                                                                                   |
| lower limit                                       | 0.86                                                                                      |
| upper limit                                       | 1.13                                                                                      |

Notes:

[22] - Non-inferiority for each common serotype was declared if the lower limit of the 2-sided 95% CI for the GMC ratio (13vPnC+P80/13vPnC-P80) > 0.5 (2-fold criterion).

|                                   |              |
|-----------------------------------|--------------|
| <b>Statistical analysis title</b> | Serotype 19F |
|-----------------------------------|--------------|

Statistical analysis description:

GMC ratio (13vPnC+P80/13vPnC-P80) was calculated.

|                                         |                                                                                           |
|-----------------------------------------|-------------------------------------------------------------------------------------------|
| Comparison groups                       | 13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series |
| Number of subjects included in analysis | 476                                                                                       |
| Analysis specification                  | Pre-specified                                                                             |
| Analysis type                           | non-inferiority <sup>[23]</sup>                                                           |
| Parameter estimate                      | GMC ratio                                                                                 |
| Point estimate                          | 0.84                                                                                      |
| Confidence interval                     |                                                                                           |
| level                                   | 95 %                                                                                      |
| sides                                   | 2-sided                                                                                   |
| lower limit                             | 0.72                                                                                      |
| upper limit                             | 0.97                                                                                      |

Notes:

[23] - Non-inferiority for each common serotype was declared if the lower limit of the 2-sided 95% CI for the GMC ratio (13vPnC+P80/13vPnC-P80) > 0.5 (2-fold criterion).

|                                   |              |
|-----------------------------------|--------------|
| <b>Statistical analysis title</b> | Serotype 23F |
|-----------------------------------|--------------|

Statistical analysis description:

GMC ratio (13vPnC+P80/13vPnC-P80) was calculated.

|                                         |                                                                                           |
|-----------------------------------------|-------------------------------------------------------------------------------------------|
| Comparison groups                       | 13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series |
| Number of subjects included in analysis | 476                                                                                       |
| Analysis specification                  | Pre-specified                                                                             |
| Analysis type                           | non-inferiority <sup>[24]</sup>                                                           |
| Parameter estimate                      | GMC ratio                                                                                 |
| Point estimate                          | 0.84                                                                                      |
| Confidence interval                     |                                                                                           |
| level                                   | 95 %                                                                                      |
| sides                                   | 2-sided                                                                                   |
| lower limit                             | 0.71                                                                                      |
| upper limit                             | 0.98                                                                                      |

Notes:

[24] - Non-inferiority for each common serotype was declared if the lower limit of the 2-sided 95% CI for the GMC ratio (13vPnC+P80/13vPnC-P80) > 0.5 (2-fold criterion).

|                                   |            |
|-----------------------------------|------------|
| <b>Statistical analysis title</b> | Serotype 1 |
|-----------------------------------|------------|

Statistical analysis description:

GMC ratio (13vPnC+P80/13vPnC-P80) was calculated.

|                                         |                                                                                           |
|-----------------------------------------|-------------------------------------------------------------------------------------------|
| Comparison groups                       | 13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series |
| Number of subjects included in analysis | 476                                                                                       |
| Analysis specification                  | Pre-specified                                                                             |
| Analysis type                           | non-inferiority <sup>[25]</sup>                                                           |
| Parameter estimate                      | GMC ratio                                                                                 |
| Point estimate                          | 0.94                                                                                      |
| Confidence interval                     |                                                                                           |
| level                                   | 95 %                                                                                      |
| sides                                   | 2-sided                                                                                   |
| lower limit                             | 0.81                                                                                      |
| upper limit                             | 1.1                                                                                       |

Notes:

[25] - Non-inferiority for each additional serotype was declared if the lower limit of the 2-sided 95% CI for the GMC ratio (13vPnC/7vPnC) > 0.5 (2-fold criterion).

| Statistical analysis title                                                             | Serotype 3                                                                                |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| Statistical analysis description:<br>GMC ratio (13vPnC+P80/13vPnC-P80) was calculated. |                                                                                           |
| Comparison groups                                                                      | 13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series |
| Number of subjects included in analysis                                                | 476                                                                                       |
| Analysis specification                                                                 | Pre-specified                                                                             |
| Analysis type                                                                          | non-inferiority <sup>[26]</sup>                                                           |
| Parameter estimate                                                                     | GMC ratio                                                                                 |
| Point estimate                                                                         | 0.93                                                                                      |
| Confidence interval                                                                    |                                                                                           |
| level                                                                                  | 95 %                                                                                      |
| sides                                                                                  | 2-sided                                                                                   |
| lower limit                                                                            | 0.83                                                                                      |
| upper limit                                                                            | 1.04                                                                                      |

Notes:

[26] - Non-inferiority for each additional serotype was declared if the lower limit of the 2-sided 95% CI for the GMC ratio (13vPnC+P80/13vPnC-P80) > 0.5 (2-fold criterion).

| Statistical analysis title                                                             | Serotype 6A                                                                               |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| Statistical analysis description:<br>GMC ratio (13vPnC+P80/13vPnC-P80) was calculated. |                                                                                           |
| Comparison groups                                                                      | 13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series |
| Number of subjects included in analysis                                                | 476                                                                                       |
| Analysis specification                                                                 | Pre-specified                                                                             |
| Analysis type                                                                          | non-inferiority <sup>[27]</sup>                                                           |
| Parameter estimate                                                                     | GMC ratio                                                                                 |
| Point estimate                                                                         | 0.96                                                                                      |
| Confidence interval                                                                    |                                                                                           |
| level                                                                                  | 95 %                                                                                      |
| sides                                                                                  | 2-sided                                                                                   |
| lower limit                                                                            | 0.81                                                                                      |
| upper limit                                                                            | 1.13                                                                                      |

Notes:

[27] - Non-inferiority for each additional serotype was declared if the lower limit of the 2-sided 95% CI for the GMC ratio (13vPnC+P80/13vPnC-P80) > 0.5 (2-fold criterion).

| Statistical analysis title                                                             | Serotype 5                                                                                |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| Statistical analysis description:<br>GMC ratio (13vPnC+P80/13vPnC-P80) was calculated. |                                                                                           |
| Comparison groups                                                                      | 13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series |
| Number of subjects included in analysis                                                | 476                                                                                       |
| Analysis specification                                                                 | Pre-specified                                                                             |
| Analysis type                                                                          | non-inferiority <sup>[28]</sup>                                                           |
| Parameter estimate                                                                     | GMC ratio                                                                                 |
| Point estimate                                                                         | 0.97                                                                                      |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.83    |
| upper limit         | 1.13    |

Notes:

[28] - Non-inferiority for each additional serotype was declared if the lower limit of the 2-sided 95% CI for the GMC ratio (13vPnC+P80/13vPnC-P80) > 0.5 (2-fold criterion).

|                                   |             |
|-----------------------------------|-------------|
| <b>Statistical analysis title</b> | Serotype 7F |
|-----------------------------------|-------------|

Statistical analysis description:

GMC ratio (13vPnC+P80/13vPnC-P80) was calculated.

|                                         |                                                                                           |
|-----------------------------------------|-------------------------------------------------------------------------------------------|
| Comparison groups                       | 13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series |
| Number of subjects included in analysis | 476                                                                                       |
| Analysis specification                  | Pre-specified                                                                             |
| Analysis type                           | non-inferiority <sup>[29]</sup>                                                           |
| Parameter estimate                      | GMC ratio                                                                                 |
| Point estimate                          | 1.05                                                                                      |

Confidence interval

|             |         |
|-------------|---------|
| level       | 95 %    |
| sides       | 2-sided |
| lower limit | 0.93    |
| upper limit | 1.18    |

Notes:

[29] - Non-inferiority for each additional serotype was declared if the lower limit of the 2-sided 95% CI for the GMC ratio (13vPnC+P80/13vPnC-P80) > 0.5 (2-fold criterion).

|                                   |              |
|-----------------------------------|--------------|
| <b>Statistical analysis title</b> | Serotype 19A |
|-----------------------------------|--------------|

Statistical analysis description:

GMC ratio (13vPnC+P80/13vPnC-P80) was calculated.

|                                         |                                                                                           |
|-----------------------------------------|-------------------------------------------------------------------------------------------|
| Comparison groups                       | 13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series |
| Number of subjects included in analysis | 476                                                                                       |
| Analysis specification                  | Pre-specified                                                                             |
| Analysis type                           | non-inferiority <sup>[30]</sup>                                                           |
| Parameter estimate                      | GMC ratio                                                                                 |
| Point estimate                          | 0.91                                                                                      |

Confidence interval

|             |         |
|-------------|---------|
| level       | 95 %    |
| sides       | 2-sided |
| lower limit | 0.8     |
| upper limit | 1.04    |

Notes:

[30] - Non-inferiority for each additional serotype was declared if the lower limit of the 2-sided 95% CI for the GMC ratio (13vPnC+P80/13vPnC-P80) > 0.5 (2-fold criterion).

## Secondary: Percentage of Subjects Achieving Antibody Level $\geq 0.35$ µg/mL in the 13vPnC Group After the Toddler Dose

|                 |                                                                                                              |
|-----------------|--------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Achieving Antibody Level $\geq 0.35$ µg/mL in the 13vPnC Group After the Toddler Dose |
|-----------------|--------------------------------------------------------------------------------------------------------------|

End point description:

Percentages of subjects achieving World Health Organization (WHO) predefined antibody threshold  $\geq 0.35$  µg/mL along with the corresponding 95% 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) are presented. Evaluable immunogenicity population had valid and determinate assay results, and had no other major protocol violations, (n) = number of subjects with a determinate IgG antibody concentration to the given serotype.

|                                                      |           |
|------------------------------------------------------|-----------|
| End point type                                       | Secondary |
| End point timeframe:                                 |           |
| 1 month after the toddler dose (at 13 months of age) |           |

| End point values                                | 13vPnC - Polysorbate 80 After Toddler Dose | 13vPnC+Polysorbate 80 After Toddler Dose |  |  |
|-------------------------------------------------|--------------------------------------------|------------------------------------------|--|--|
| Subject group type                              | Reporting group                            | Reporting group                          |  |  |
| Number of subjects analysed                     | 238 <sup>[31]</sup>                        | 227 <sup>[32]</sup>                      |  |  |
| Units: percentage of subjects                   |                                            |                                          |  |  |
| number (confidence interval 95%)                |                                            |                                          |  |  |
| Common Serotypes - Serotype 4 (n=226,238)       | 99.6 (97.7 to 100)                         | 99.6 (97.6 to 100)                       |  |  |
| Common Serotypes - Serotype 6B (n=225,237)      | 99.2 (97 to 99.9)                          | 99.6 (97.5 to 100)                       |  |  |
| Common Serotypes - Serotype 9V (n=226,238)      | 100 (98.5 to 100)                          | 99.6 (97.6 to 100)                       |  |  |
| Common Serotypes - Serotype 14 (n=226,238)      | 99.6 (97.7 to 100)                         | 99.6 (97.6 to 100)                       |  |  |
| Common Serotypes - Serotype 18C (n=226,238)     | 99.6 (97.7 to 100)                         | 100 (98.4 to 100)                        |  |  |
| Common Serotypes - Serotype 19F (n=226,237)     | 98.7 (96.3 to 99.7)                        | 99.1 (96.8 to 99.9)                      |  |  |
| Common Serotypes - Serotype 23F (n=226,238)     | 99.6 (97.7 to 100)                         | 98.7 (96.2 to 99.7)                      |  |  |
| Additional Serotypes - Serotype 1 (n=226,238)   | 99.2 (97 to 99.9)                          | 100 (98.4 to 100)                        |  |  |
| Additional Serotypes - Serotype 3 (n=223,236)   | 94.5 (90.8 to 97)                          | 95.1 (91.3 to 97.5)                      |  |  |
| Additional Serotypes - Serotype 5 (n=226,238)   | 100 (98.5 to 100)                          | 99.6 (97.6 to 100)                       |  |  |
| Additional Serotypes - Serotype 6A (n=226,237)  | 100 (98.5 to 100)                          | 99.6 (97.6 to 100)                       |  |  |
| Additional Serotypes - Serotype 7F (n=226,238)  | 100 (98.5 to 100)                          | 100 (98.4 to 100)                        |  |  |
| Additional Serotypes - Serotype 19A (n=226,238) | 100 (98.5 to 100)                          | 100 (98.4 to 100)                        |  |  |

Notes:

[31] - Subjects with a determinate antibody concentration for the specified serotype.

[32] - Subjects with a determinate antibody concentration for the specified serotype.

## Statistical analyses

|                                                                                            |                                                                                       |
|--------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| Statistical analysis title                                                                 | Serotype 4                                                                            |
| Statistical analysis description:                                                          |                                                                                       |
| Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated. |                                                                                       |
| Comparison groups                                                                          | 13vPnC+Polysorbate 80 After Toddler Dose v 13vPnC - Polysorbate 80 After Toddler Dose |

|                                         |                                 |
|-----------------------------------------|---------------------------------|
| Number of subjects included in analysis | 465                             |
| Analysis specification                  | Pre-specified                   |
| Analysis type                           | non-inferiority <sup>[33]</sup> |
| Parameter estimate                      | Difference in percentage        |
| Point estimate                          | 0                               |
| Confidence interval                     |                                 |
| level                                   | 95 %                            |
| sides                                   | 2-sided                         |
| lower limit                             | -2.1                            |
| upper limit                             | 1.9                             |

Notes:

[33] - Non-inferiority for each common serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

|                                   |             |
|-----------------------------------|-------------|
| <b>Statistical analysis title</b> | Serotype 6B |
|-----------------------------------|-------------|

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

|                                         |                                                                                       |
|-----------------------------------------|---------------------------------------------------------------------------------------|
| Comparison groups                       | 13vPnC+Polysorbate 80 After Toddler Dose v 13vPnC - Polysorbate 80 After Toddler Dose |
| Number of subjects included in analysis | 465                                                                                   |
| Analysis specification                  | Pre-specified                                                                         |
| Analysis type                           | non-inferiority <sup>[34]</sup>                                                       |
| Parameter estimate                      | Difference in percentage                                                              |
| Point estimate                          | 0.4                                                                                   |
| Confidence interval                     |                                                                                       |
| level                                   | 95 %                                                                                  |
| sides                                   | 2-sided                                                                               |
| lower limit                             | -1.7                                                                                  |
| upper limit                             | 2.6                                                                                   |

Notes:

[34] - Non-inferiority for each common serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

|                                   |             |
|-----------------------------------|-------------|
| <b>Statistical analysis title</b> | Serotype 9V |
|-----------------------------------|-------------|

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated

|                                         |                                                                                       |
|-----------------------------------------|---------------------------------------------------------------------------------------|
| Comparison groups                       | 13vPnC+Polysorbate 80 After Toddler Dose v 13vPnC - Polysorbate 80 After Toddler Dose |
| Number of subjects included in analysis | 465                                                                                   |
| Analysis specification                  | Pre-specified                                                                         |
| Analysis type                           | non-inferiority <sup>[35]</sup>                                                       |
| Parameter estimate                      | Difference in percentage                                                              |
| Point estimate                          | -0.4                                                                                  |
| Confidence interval                     |                                                                                       |
| level                                   | 95 %                                                                                  |
| sides                                   | 2-sided                                                                               |
| lower limit                             | -2.4                                                                                  |
| upper limit                             | 1.1                                                                                   |

Notes:

[35] - Non-inferiority for each common serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

|                                   |             |
|-----------------------------------|-------------|
| <b>Statistical analysis title</b> | Serotype 14 |
|-----------------------------------|-------------|

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

|                                         |                                                                                       |
|-----------------------------------------|---------------------------------------------------------------------------------------|
| Comparison groups                       | 13vPnC+Polysorbate 80 After Toddler Dose v 13vPnC - Polysorbate 80 After Toddler Dose |
| Number of subjects included in analysis | 465                                                                                   |
| Analysis specification                  | Pre-specified                                                                         |
| Analysis type                           | non-inferiority <sup>[36]</sup>                                                       |
| Parameter estimate                      | Difference in percentage                                                              |
| Point estimate                          | 0                                                                                     |
| Confidence interval                     |                                                                                       |
| level                                   | 95 %                                                                                  |
| sides                                   | 2-sided                                                                               |
| lower limit                             | -2.1                                                                                  |
| upper limit                             | 1.9                                                                                   |

Notes:

[36] - Non-inferiority for each common serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

|                                   |              |
|-----------------------------------|--------------|
| <b>Statistical analysis title</b> | Serotype 18C |
|-----------------------------------|--------------|

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

|                                         |                                                                                       |
|-----------------------------------------|---------------------------------------------------------------------------------------|
| Comparison groups                       | 13vPnC+Polysorbate 80 After Toddler Dose v 13vPnC - Polysorbate 80 After Toddler Dose |
| Number of subjects included in analysis | 465                                                                                   |
| Analysis specification                  | Pre-specified                                                                         |
| Analysis type                           | non-inferiority <sup>[37]</sup>                                                       |
| Parameter estimate                      | Difference in percentage                                                              |
| Point estimate                          | 0.4                                                                                   |
| Confidence interval                     |                                                                                       |
| level                                   | 95 %                                                                                  |
| sides                                   | 2-sided                                                                               |
| lower limit                             | -1.2                                                                                  |
| upper limit                             | 2.3                                                                                   |

Notes:

[37] - Non-inferiority for each common serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

|                                   |              |
|-----------------------------------|--------------|
| <b>Statistical analysis title</b> | Serotype 19F |
|-----------------------------------|--------------|

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

|                                         |                                                                                       |
|-----------------------------------------|---------------------------------------------------------------------------------------|
| Comparison groups                       | 13vPnC+Polysorbate 80 After Toddler Dose v 13vPnC - Polysorbate 80 After Toddler Dose |
| Number of subjects included in analysis | 465                                                                                   |
| Analysis specification                  | Pre-specified                                                                         |
| Analysis type                           | non-inferiority <sup>[38]</sup>                                                       |
| Parameter estimate                      | Difference in percentage                                                              |
| Point estimate                          | 0.4                                                                                   |
| Confidence interval                     |                                                                                       |
| level                                   | 95 %                                                                                  |
| sides                                   | 2-sided                                                                               |
| lower limit                             | -2                                                                                    |
| upper limit                             | 2.9                                                                                   |

Notes:

[38] - Non-inferiority for each common serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

|                                                                                            |                                                                                       |
|--------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| <b>Statistical analysis title</b>                                                          | Serotype 23F                                                                          |
| Statistical analysis description:                                                          |                                                                                       |
| Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated. |                                                                                       |
| Comparison groups                                                                          | 13vPnC+Polysorbate 80 After Toddler Dose v 13vPnC - Polysorbate 80 After Toddler Dose |
| Number of subjects included in analysis                                                    | 465                                                                                   |
| Analysis specification                                                                     | Pre-specified                                                                         |
| Analysis type                                                                              | non-inferiority <sup>[39]</sup>                                                       |
| Parameter estimate                                                                         | Difference in percentage                                                              |
| Point estimate                                                                             | -0.9                                                                                  |
| Confidence interval                                                                        |                                                                                       |
| level                                                                                      | 95 %                                                                                  |
| sides                                                                                      | 2-sided                                                                               |
| lower limit                                                                                | -3.4                                                                                  |
| upper limit                                                                                | 1.1                                                                                   |

Notes:

[39] - Non-inferiority for each common serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

|                                                                                            |                                                                                       |
|--------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| <b>Statistical analysis title</b>                                                          | Serotype 1                                                                            |
| Statistical analysis description:                                                          |                                                                                       |
| Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated. |                                                                                       |
| Comparison groups                                                                          | 13vPnC+Polysorbate 80 After Toddler Dose v 13vPnC - Polysorbate 80 After Toddler Dose |
| Number of subjects included in analysis                                                    | 465                                                                                   |
| Analysis specification                                                                     | Pre-specified                                                                         |
| Analysis type                                                                              | non-inferiority <sup>[40]</sup>                                                       |
| Parameter estimate                                                                         | Difference in percentage                                                              |
| Point estimate                                                                             | 0.8                                                                                   |
| Confidence interval                                                                        |                                                                                       |
| level                                                                                      | 95 %                                                                                  |
| sides                                                                                      | 2-sided                                                                               |
| lower limit                                                                                | -0.8                                                                                  |
| upper limit                                                                                | 3                                                                                     |

Notes:

[40] - Non-inferiority for each additional serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

|                                                                                            |                                                                                       |
|--------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| <b>Statistical analysis title</b>                                                          | Serotype 3                                                                            |
| Statistical analysis description:                                                          |                                                                                       |
| Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated. |                                                                                       |
| Comparison groups                                                                          | 13vPnC+Polysorbate 80 After Toddler Dose v 13vPnC - Polysorbate 80 After Toddler Dose |
| Number of subjects included in analysis                                                    | 465                                                                                   |
| Analysis specification                                                                     | Pre-specified                                                                         |
| Analysis type                                                                              | non-inferiority <sup>[41]</sup>                                                       |
| Parameter estimate                                                                         | Difference in percentage                                                              |
| Point estimate                                                                             | 0.6                                                                                   |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | -3.7    |
| upper limit         | 4.9     |

Notes:

[41] - Non-inferiority for each additional serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

|                                   |            |
|-----------------------------------|------------|
| <b>Statistical analysis title</b> | Serotype 5 |
|-----------------------------------|------------|

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

|                                         |                                                                                       |
|-----------------------------------------|---------------------------------------------------------------------------------------|
| Comparison groups                       | 13vPnC+Polysorbate 80 After Toddler Dose v 13vPnC - Polysorbate 80 After Toddler Dose |
| Number of subjects included in analysis | 465                                                                                   |
| Analysis specification                  | Pre-specified                                                                         |
| Analysis type                           | non-inferiority <sup>[42]</sup>                                                       |
| Parameter estimate                      | Difference in percentage                                                              |
| Point estimate                          | -0.4                                                                                  |

Confidence interval

|             |         |
|-------------|---------|
| level       | 95 %    |
| sides       | 2-sided |
| lower limit | -2.4    |
| upper limit | 1.1     |

Notes:

[42] - Non-inferiority for each additional serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

|                                   |             |
|-----------------------------------|-------------|
| <b>Statistical analysis title</b> | Serotype 6A |
|-----------------------------------|-------------|

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

|                                         |                                                                                       |
|-----------------------------------------|---------------------------------------------------------------------------------------|
| Comparison groups                       | 13vPnC+Polysorbate 80 After Toddler Dose v 13vPnC - Polysorbate 80 After Toddler Dose |
| Number of subjects included in analysis | 465                                                                                   |
| Analysis specification                  | Pre-specified                                                                         |
| Analysis type                           | non-inferiority <sup>[43]</sup>                                                       |
| Parameter estimate                      | Difference in percentage                                                              |
| Point estimate                          | -0.4                                                                                  |

Confidence interval

|             |         |
|-------------|---------|
| level       | 95 %    |
| sides       | 2-sided |
| lower limit | -2.4    |
| upper limit | 1.2     |

Notes:

[43] - Non-inferiority for each additional serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

|                                   |             |
|-----------------------------------|-------------|
| <b>Statistical analysis title</b> | Serotype 7F |
|-----------------------------------|-------------|

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

|                   |                                                                                       |
|-------------------|---------------------------------------------------------------------------------------|
| Comparison groups | 13vPnC+Polysorbate 80 After Toddler Dose v 13vPnC - Polysorbate 80 After Toddler Dose |
|-------------------|---------------------------------------------------------------------------------------|

|                                         |                                 |
|-----------------------------------------|---------------------------------|
| Number of subjects included in analysis | 465                             |
| Analysis specification                  | Pre-specified                   |
| Analysis type                           | non-inferiority <sup>[44]</sup> |
| Parameter estimate                      | Difference in percentage        |
| Point estimate                          | 0                               |
| Confidence interval                     |                                 |
| level                                   | 95 %                            |
| sides                                   | 2-sided                         |
| lower limit                             | -1.7                            |
| upper limit                             | 1.6                             |

Notes:

[44] - Non-inferiority for each additional serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

|                                   |              |
|-----------------------------------|--------------|
| <b>Statistical analysis title</b> | Serotype 19A |
|-----------------------------------|--------------|

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

|                                         |                                                                                       |
|-----------------------------------------|---------------------------------------------------------------------------------------|
| Comparison groups                       | 13vPnC+Polysorbate 80 After Toddler Dose v 13vPnC - Polysorbate 80 After Toddler Dose |
| Number of subjects included in analysis | 465                                                                                   |
| Analysis specification                  | Pre-specified                                                                         |
| Analysis type                           | non-inferiority <sup>[45]</sup>                                                       |
| Parameter estimate                      | Difference in percentage                                                              |
| Point estimate                          | 0                                                                                     |
| Confidence interval                     |                                                                                       |
| level                                   | 95 %                                                                                  |
| sides                                   | 2-sided                                                                               |
| lower limit                             | -1.7                                                                                  |
| upper limit                             | 1.6                                                                                   |

Notes:

[45] - Non-inferiority for each additional serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

### **Secondary: Geometric Mean Antibody Concentration (GMC) in 13vPnC Group Relative After the Toddler Dose**

|                 |                                                                                             |
|-----------------|---------------------------------------------------------------------------------------------|
| End point title | Geometric Mean Antibody Concentration (GMC) in 13vPnC Group Relative After the Toddler Dose |
|-----------------|---------------------------------------------------------------------------------------------|

End point description:

GMC as measured by enzyme-linked immunosorbent assay (ELISA) for 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) are presented. Evaluable immunogenicity population had valid and determinate assay results, and had no other major protocol violations, (n) = number of subjects with a determinate IgG antibody concentration for the specified serotype.

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

End point timeframe:

1 month after the toddler dose (at 13 months of age)

| End point values                                | 13vPnC - Polysorbate 80 After Toddler Dose | 13vPnC+Polysorbate 80 After Toddler Dose |  |  |
|-------------------------------------------------|--------------------------------------------|------------------------------------------|--|--|
| Subject group type                              | Reporting group                            | Reporting group                          |  |  |
| Number of subjects analysed                     | 227                                        | 238                                      |  |  |
| Units: µg/mL                                    |                                            |                                          |  |  |
| geometric mean (confidence interval 95%)        |                                            |                                          |  |  |
| Common Serotypes - Serotype 4 (n=226,238)       | 13.2 (4.65 to 5.92)                        | 5.38 (4.78 to 6.07)                      |  |  |
| Common Serotypes - Serotype 6B (n=225,237)      | 5.25 (8.7 to 11.23)                        | 10.65 (9.4 to 12.06)                     |  |  |
| Common Serotypes - Serotype 9V (n=226,238)      | 9.89 (2.73 to 3.31)                        | 3.1 (2.8 to 3.42)                        |  |  |
| Common Serotypes - Serotype 14 (n=226,238)      | 3.01 (10.26 to 13.4)                       | 11.95 (10.42 to 13.71)                   |  |  |
| Common Serotypes - Serotype 18C (n=226,238)     | 11.72 (3.06 to 3.78)                       | 3.1 (2.79 to 3.45)                       |  |  |
| Common Serotypes - Serotype 19F (n=226,238)     | 3.4 (8.45 to 10.97)                        | 10.27 (8.99 to 11.73)                    |  |  |
| Common Serotypes - Serotype 23F (n=226,238)     | 9.63 (3.44 to 4.38)                        | 4.15 (3.73 to 4.62)                      |  |  |
| Additional Serotypes - Serotype 1 (n=226,238)   | 3.88 (5.36 to 6.78)                        | 6.11 (5.43 to 6.87)                      |  |  |
| Additional Serotypes - Serotype 3 (n=223,236)   | 6.03 (0.99 to 1.2)                         | 1.16 (1.05 to 1.29)                      |  |  |
| Additional Serotypes - Serotype 5 (n=226,238)   | 1.09 (3.41 to 4.23)                        | 3.98 (3.59 to 4.41)                      |  |  |
| Additional Serotypes - Serotype 6A (n=226,237)  | 3.8 (6.66 to 8.4)                          | 8.19 (7.38 to 9.09)                      |  |  |
| Additional Serotypes - Serotype 7F (n=226,238)  | 7.48 (4.89 to 5.88)                        | 4.95 (4.5 to 5.44)                       |  |  |
| Additional Serotypes - Serotype 19A (n=226,238) | 5.36 (11.88 to 14.67)                      | 13.02 (11.88 to 14.27)                   |  |  |

## Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Percent of Subjects Reporting Pre-Specified Local Reactions

| End point title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Percent of Subjects Reporting Pre-Specified Local Reactions |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|
| End point description:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                             |
| Local reactions were collected using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant (Sig) (present and interfered with limb movement). Swelling and redness were scaled as Any (swelling or redness present); Mild (0.5 centimeters [cm] to 2.0 cm); Moderate (Mod) (2.5 to 7.0 cm); Severe (>7.0 cm). Subjects may be represented in more than 1 category. The safety population included all subjects who received at least 1 dose of vaccine, (n) = number of subjects reporting yes for at least 1 day or no for all days. |                                                             |
| End point type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Other pre-specified                                         |
| End point timeframe:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                             |
| Within 4-days after each dose                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                             |

| End point values                                      | 13vPnC + P80<br>Dose 1 Infant<br>Series | 13vPnC - P 80<br>Dose 1 Infant<br>Series | 13vPnC + P80<br>Dose 2 Infant<br>Series | 13vPnC - P80<br>Dose 2 Infant<br>Series |
|-------------------------------------------------------|-----------------------------------------|------------------------------------------|-----------------------------------------|-----------------------------------------|
| Subject group type                                    | Subject analysis set                    | Subject analysis set                     | Subject analysis set                    | Subject analysis set                    |
| Number of subjects analysed                           | 250                                     | 250                                      | 246                                     | 249                                     |
| Units: percentage of subjects                         |                                         |                                          |                                         |                                         |
| number (not applicable)                               |                                         |                                          |                                         |                                         |
| Tenderness-Any<br>(n=238,237,228,229,210,216,178,188) | 27.7                                    | 32.9                                     | 26.8                                    | 32.8                                    |
| Tenderness-Sig<br>(n=235,233,220,221,203,211,160,165) | 2.1                                     | 4.3                                      | 0.9                                     | 0.5                                     |
| Swelling-Any<br>(n=236,239,228,228,210,225,174,181)   | 22.9                                    | 30.5                                     | 25                                      | 36.4                                    |
| Swelling-Mild<br>(n=236,236,227,226,209,221,169,178)  | 18.2                                    | 24.2                                     | 20.3                                    | 31.9                                    |
| Swelling-Mod<br>(n=236,236,224,224,208,217,164,171)   | 11.9                                    | 14.4                                     | 11.2                                    | 14.3                                    |
| Swelling-<br>Severe(n=235,233,220,221,203,211,15      | 0                                       | 0                                        | 0                                       | 0                                       |
| Redness-Any<br>(n=238,238,232,231,216,226,178,200)    | 29.8                                    | 39.5                                     | 38.8                                    | 48.5                                    |
| Redness-Mild<br>(n=238,235,232,230,215,226,176,194)   | 28.2                                    | 35.7                                     | 38.4                                    | 47                                      |
| Redness-Mod<br>(n=235,232,220,222,206,211,164,173)    | 2.1                                     | 4.3                                      | 1.4                                     | 3.2                                     |
| Redness-Severe<br>(n=235,231,220,221,203,211,159,164) | 0                                       | 0                                        | 0                                       | 0                                       |

| End point values                                      | 13vPnC + P80<br>Dose 3 Infant<br>Series | 13vPnC - P80<br>Dose 3 Infant<br>Series | 13vPnC + P80<br>Toddler Dose | 13vPnC - P80<br>Toddler Dose |
|-------------------------------------------------------|-----------------------------------------|-----------------------------------------|------------------------------|------------------------------|
| Subject group type                                    | Subject analysis set                    | Subject analysis set                    | Subject analysis set         | Subject analysis set         |
| Number of subjects analysed                           | 246                                     | 247                                     | 240                          | 244                          |
| Units: percentage of subjects                         |                                         |                                         |                              |                              |
| number (not applicable)                               |                                         |                                         |                              |                              |
| Tenderness-Any<br>(n=238,237,228,229,210,216,178,188) | 24.8                                    | 23.1                                    | 42.1                         | 43.1                         |
| Tenderness-Sig<br>(n=235,233,220,221,203,211,160,165) | 1.5                                     | 1.9                                     | 2.5                          | 1.2                          |
| Swelling-Any<br>(n=236,239,228,228,210,225,174,181)   | 36.7                                    | 38.2                                    | 29.9                         | 34.8                         |
| Swelling-Mild<br>(n=236,236,227,226,209,221,169,178)  | 32.5                                    | 33.5                                    | 26.6                         | 29.8                         |
| Swelling-Mod<br>(n=236,236,224,224,208,217,164,171)   | 13.9                                    | 17.5                                    | 12.2                         | 19.9                         |
| Swelling-<br>Severe(n=235,233,220,221,203,211,15      | 0                                       | 0                                       | 0                            | 0                            |
| Redness-Any<br>(n=238,238,232,231,216,226,178,200)    | 46.8                                    | 50                                      | 42.1                         | 52                           |
| Redness-Mild<br>(n=238,235,232,230,215,226,176,194)   | 46.5                                    | 46.9                                    | 35.8                         | 46.4                         |
| Redness-Mod<br>(n=235,232,220,222,206,211,164,173)    | 3.9                                     | 9                                       | 12.8                         | 19.7                         |
| Redness-Severe<br>(n=235,231,220,221,203,211,159,164) | 0                                       | 0                                       | 0                            | 0.6                          |

## Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Percentage of Subjects Reporting Pre-Specified Systemic Events

|                 |                                                                |
|-----------------|----------------------------------------------------------------|
| End point title | Percentage of Subjects Reporting Pre-Specified Systemic Events |
|-----------------|----------------------------------------------------------------|

End point description:

Systemic events (fever [Fv]  $\geq 37.5$  degrees Celsius [C], fever  $\geq 38$  C but  $\leq 39$  C, fever  $>39$  C but  $\leq 40$  C, fever  $> 40$  C, decreased (decr) appetite, irritability, increased (incr)sleep, decreased sleep, hives, use of medication (meds) to treat symptoms (sx), and use of medication to prevent symptoms) were reported using an electronic diary. Subjects may be represented in more than 1 category. The safety population included all subjects who received at least 1 dose of vaccine, (n) = number of subjects reporting yes for at least 1 day or no for all days.

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

End point timeframe:

Within 4-days after each dose

| End point values                                                                          | 13vPnC + P80<br>Dose 1 Infant<br>Series | 13vPnC - P 80<br>Dose 1 Infant<br>Series | 13vPnC + P80<br>Dose 2 Infant<br>Series | 13vPnC - P80<br>Dose 2 Infant<br>Series |
|-------------------------------------------------------------------------------------------|-----------------------------------------|------------------------------------------|-----------------------------------------|-----------------------------------------|
| Subject group type                                                                        | Subject analysis set                    | Subject analysis set                     | Subject analysis set                    | Subject analysis set                    |
| Number of subjects analysed                                                               | 250                                     | 250                                      | 246                                     | 249                                     |
| Units: percentage of subjects                                                             |                                         |                                          |                                         |                                         |
| number (not applicable)                                                                   |                                         |                                          |                                         |                                         |
| Fv $\geq 38^{\circ}\text{C}$ ,<br>$\leq 39^{\circ}\text{C}$ (n=236,235,224,229,208,218,17 | 14                                      | 16.2                                     | 18.3                                    | 17                                      |
| Fv $>39^{\circ}\text{C}$ ,<br>$\leq 40^{\circ}\text{C}$ (n=235,233,221,221,203,211,16     | 0.4                                     | 0.4                                      | 0.9                                     | 0.5                                     |
| Fv $>40^{\circ}\text{C}$<br>(n=235,233,221,221,203,211,160,164)                           | 0                                       | 0                                        | 0                                       | 0                                       |
| Decr appetite<br>(n=237,237,221,224,210,222,172,183)                                      | 21.5                                    | 22.4                                     | 16.3                                    | 24.1                                    |
| Irritability<br>(n=240,239,232,232,215,226,184,198)                                       | 55                                      | 55.2                                     | 51.7                                    | 53.9                                    |
| Incr sleep<br>(n=242,242,231,229,209,221,174,182)                                         | 46.3                                    | 52.5                                     | 35.9                                    | 39.3                                    |
| Decr sleep<br>(n=238,236,227,227,209,217,170,180)                                         | 35.7                                    | 29.7                                     | 24.7                                    | 26.4                                    |
| Meds-treat sx<br>(n=236,235,222,226,205,218,172,168)                                      | 14                                      | 16.6                                     | 15.3                                    | 16.8                                    |
| Meds-prevent<br>sx(n=235,234,220,223,205,217,171,17                                       | 14.5                                    | 15.8                                     | 16.4                                    | 15.2                                    |

| End point values                                                                          | 13vPnC + P80<br>Dose 3 Infant<br>Series | 13vPnC - P80<br>Dose 3 Infant<br>Series | 13vPnC + P80<br>Toddler Dose | 13vPnC - P80<br>Toddler Dose |
|-------------------------------------------------------------------------------------------|-----------------------------------------|-----------------------------------------|------------------------------|------------------------------|
| Subject group type                                                                        | Subject analysis set                    | Subject analysis set                    | Subject analysis set         | Subject analysis set         |
| Number of subjects analysed                                                               | 246                                     | 247                                     | 240                          | 244                          |
| Units: percentage of subjects                                                             |                                         |                                         |                              |                              |
| number (not applicable)                                                                   |                                         |                                         |                              |                              |
| Fv $\geq 38^{\circ}\text{C}$ ,<br>$\leq 39^{\circ}\text{C}$ (n=236,235,224,229,208,218,17 | 19.7                                    | 20.6                                    | 22.9                         | 18                           |
| Fv $> 39^{\circ}\text{C}$ ,<br>$\leq 40^{\circ}\text{C}$ (n=235,233,221,221,203,211,16    | 1                                       | 0.9                                     | 2.5                          | 1.8                          |
| Fv $> 40^{\circ}\text{C}$<br>(n=235,233,221,221,203,211,160,164)                          | 0                                       | 0                                       | 0                            | 0                            |
| Decr appetite<br>(n=237,237,221,224,210,222,172,183)                                      | 21.4                                    | 20.7                                    | 26.2                         | 29                           |
| Irritability<br>(n=240,239,232,232,215,226,184,198)                                       | 45.6                                    | 50                                      | 49.5                         | 56.1                         |
| Incr sleep<br>(n=242,242,231,229,209,221,174,182)                                         | 25.8                                    | 27.6                                    | 19                           | 30.8                         |
| Decr sleep<br>(n=238,236,227,227,209,217,170,180)                                         | 25.4                                    | 24.4                                    | 19.4                         | 25.6                         |
| Meds-treat sx<br>(n=236,235,222,226,205,218,172,168)                                      | 15.1                                    | 14.7                                    | 21.5                         | 15.5                         |
| Meds-prevent<br>sx(n=235,234,220,223,205,217,171,17                                       | 15.1                                    | 10.6                                    | 18.7                         | 15.2                         |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Baseline up to 6 months after the last administration of study drug

Adverse event reporting additional description:

EU BR specific AE tables were generated separately as per EU format. Latest coding dictionary has been used for EU BR tables.

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 17.1 |
|--------------------|------|

### Reporting groups

|                       |                            |
|-----------------------|----------------------------|
| Reporting group title | 13vPnC + P80 Infant Series |
|-----------------------|----------------------------|

Reporting group description:

Subjects received one single 0.5mL dose of 13vPnC + P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months age (infant doses).

|                       |                             |
|-----------------------|-----------------------------|
| Reporting group title | 13vPnC - P 80 Infant Series |
|-----------------------|-----------------------------|

Reporting group description:

Subjects received one single 0.5mL dose of 13vPnC - P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months age (infant doses).

|                       |                                 |
|-----------------------|---------------------------------|
| Reporting group title | 13vPnC + P80 Post-Infant Series |
|-----------------------|---------------------------------|

Reporting group description:

Subjects received one single 0.5mL dose of 13vPnC + P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months age (infant doses).

|                       |                                 |
|-----------------------|---------------------------------|
| Reporting group title | 13vPnC - P80 Post-Infant Series |
|-----------------------|---------------------------------|

Reporting group description:

Subjects received one single 0.5mL dose of 13vPnC - P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months age (infant doses).

|                       |                           |
|-----------------------|---------------------------|
| Reporting group title | 13vPnC - P80 Toddler Dose |
|-----------------------|---------------------------|

Reporting group description:

Subjects received one single 0.5mL dose of 13vPnC - P80 coadministered with Priorix at 12 months of age (toddler dose).

|                       |                           |
|-----------------------|---------------------------|
| Reporting group title | 13vPnC + P80 Toddler Dose |
|-----------------------|---------------------------|

Reporting group description:

Subjects received one single 0.5mL dose of 13vPnC + P80 coadministered with Priorix at 12 months of age (toddler dose).

|                       |                                |
|-----------------------|--------------------------------|
| Reporting group title | 13vPnC + P80 6-Month Follow-up |
|-----------------------|--------------------------------|

Reporting group description:

Subjects received one single 0.5mL dose of 13vPnC + P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months age (infant doses), and Priorix at 12 months of age (toddler dose).

|                       |                                |
|-----------------------|--------------------------------|
| Reporting group title | 13vPnC - P80 6-Month Follow-up |
|-----------------------|--------------------------------|

Reporting group description:

Subjects received one single 0.5mL dose of 13vPnC - P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months age (infant doses), and Priorix at 12 months of age (toddler dose).

| <b>Serious adverse events</b>                                          | 13vPnC + P80<br>Infant Series | 13vPnC - P 80 Infant<br>Series | 13vPnC + P80 Post-<br>Infant Series |
|------------------------------------------------------------------------|-------------------------------|--------------------------------|-------------------------------------|
| Total subjects affected by serious<br>adverse events                   |                               |                                |                                     |
| subjects affected / exposed                                            | 15 / 249 (6.02%)              | 21 / 250 (8.40%)               | 24 / 249 (9.64%)                    |
| number of deaths (all causes)                                          | 0                             | 0                              | 0                                   |
| number of deaths resulting from<br>adverse events                      | 0                             | 0                              | 0                                   |
| Neoplasms benign, malignant and<br>unspecified (incl cysts and polyps) |                               |                                |                                     |
| Renal neoplasm                                                         |                               |                                |                                     |
| alternative assessment type:<br>Systematic                             |                               |                                |                                     |
| subjects affected / exposed                                            | 0 / 249 (0.00%)               | 0 / 250 (0.00%)                | 0 / 249 (0.00%)                     |
| occurrences causally related to<br>treatment / all                     | 0 / 0                         | 0 / 0                          | 0 / 0                               |
| deaths causally related to<br>treatment / all                          | 0 / 0                         | 0 / 0                          | 0 / 0                               |
| General disorders and administration<br>site conditions                |                               |                                |                                     |
| Fibrosis                                                               |                               |                                |                                     |
| alternative assessment type:<br>Systematic                             |                               |                                |                                     |
| subjects affected / exposed                                            | 0 / 249 (0.00%)               | 0 / 250 (0.00%)                | 0 / 249 (0.00%)                     |
| occurrences causally related to<br>treatment / all                     | 0 / 0                         | 0 / 0                          | 0 / 0                               |
| deaths causally related to<br>treatment / all                          | 0 / 0                         | 0 / 0                          | 0 / 0                               |
| Pyrexia                                                                |                               |                                |                                     |
| alternative assessment type:<br>Systematic                             |                               |                                |                                     |
| subjects affected / exposed                                            | 0 / 249 (0.00%)               | 0 / 250 (0.00%)                | 0 / 249 (0.00%)                     |
| occurrences causally related to<br>treatment / all                     | 0 / 0                         | 0 / 0                          | 0 / 0                               |
| deaths causally related to<br>treatment / all                          | 0 / 0                         | 0 / 0                          | 0 / 0                               |
| Immune system disorders                                                |                               |                                |                                     |
| Alloimmunisation                                                       |                               |                                |                                     |
| alternative assessment type:<br>Systematic                             |                               |                                |                                     |
| subjects affected / exposed                                            | 0 / 249 (0.00%)               | 0 / 250 (0.00%)                | 1 / 249 (0.40%)                     |
| occurrences causally related to<br>treatment / all                     | 0 / 0                         | 0 / 0                          | 0 / 1                               |
| deaths causally related to<br>treatment / all                          | 0 / 0                         | 0 / 0                          | 0 / 0                               |
| Hypersensitivity                                                       |                               |                                |                                     |
| alternative assessment type:<br>Systematic                             |                               |                                |                                     |
| subjects affected / exposed                                            | 1 / 249 (0.40%)               | 0 / 250 (0.00%)                | 0 / 249 (0.00%)                     |
| occurrences causally related to<br>treatment / all                     | 0 / 1                         | 0 / 0                          | 0 / 0                               |
| deaths causally related to<br>treatment / all                          | 0 / 0                         | 0 / 0                          | 0 / 0                               |
| Respiratory, thoracic and mediastinal                                  |                               |                                |                                     |

|                                                    |                 |                 |                 |
|----------------------------------------------------|-----------------|-----------------|-----------------|
| disorders                                          |                 |                 |                 |
| Bronchospasm                                       |                 |                 |                 |
| alternative assessment type:<br>Systematic         |                 |                 |                 |
| subjects affected / exposed                        | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 0 / 249 (0.00%) |
| occurrences causally related to<br>treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Pneumonia aspiration                               |                 |                 |                 |
| alternative assessment type:<br>Systematic         |                 |                 |                 |
| subjects affected / exposed                        | 1 / 249 (0.40%) | 1 / 250 (0.40%) | 0 / 249 (0.00%) |
| occurrences causally related to<br>treatment / all | 0 / 1           | 0 / 1           | 0 / 0           |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Sleep apnoea syndrome                              |                 |                 |                 |
| alternative assessment type:<br>Systematic         |                 |                 |                 |
| subjects affected / exposed                        | 0 / 249 (0.00%) | 1 / 250 (0.40%) | 0 / 249 (0.00%) |
| occurrences causally related to<br>treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Psychiatric disorders                              |                 |                 |                 |
| Breath holding                                     |                 |                 |                 |
| alternative assessment type:<br>Systematic         |                 |                 |                 |
| subjects affected / exposed                        | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 1 / 249 (0.40%) |
| occurrences causally related to<br>treatment / all | 0 / 0           | 0 / 0           | 0 / 2           |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Investigations                                     |                 |                 |                 |
| Ultrasound kidney abnormal                         |                 |                 |                 |
| alternative assessment type:<br>Systematic         |                 |                 |                 |
| subjects affected / exposed                        | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 0 / 249 (0.00%) |
| occurrences causally related to<br>treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Injury, poisoning and procedural<br>complications  |                 |                 |                 |
| Head injury                                        |                 |                 |                 |
| alternative assessment type:<br>Systematic         |                 |                 |                 |
| subjects affected / exposed                        | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 2 / 249 (0.80%) |
| occurrences causally related to<br>treatment / all | 0 / 0           | 0 / 0           | 0 / 2           |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |

|                                                                                                                                                                                                                                  |                                   |                                   |                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|
| Limbic traumatic amputation<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences causally related to<br>treatment / all<br>deaths causally related to<br>treatment / all                  | 0 / 249 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 250 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 249 (0.00%)<br>0 / 0<br>0 / 0 |
| Radius fracture<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences causally related to<br>treatment / all<br>deaths causally related to<br>treatment / all                              | 0 / 249 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 250 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 249 (0.00%)<br>0 / 0<br>0 / 0 |
| Thermal burn<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences causally related to<br>treatment / all<br>deaths causally related to<br>treatment / all                                 | 0 / 249 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 250 (0.00%)<br>0 / 0<br>0 / 0 | 1 / 249 (0.40%)<br>0 / 1<br>0 / 0 |
| Nervous system disorders<br>Balance disorder<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences causally related to<br>treatment / all<br>deaths causally related to<br>treatment / all | 0 / 249 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 250 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 249 (0.00%)<br>0 / 0<br>0 / 0 |
| Febrile convulsion<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences causally related to<br>treatment / all<br>deaths causally related to<br>treatment / all                           | 0 / 249 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 250 (0.00%)<br>0 / 0<br>0 / 0 | 1 / 249 (0.40%)<br>0 / 3<br>0 / 0 |
| Hydrocephalus<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences causally related to<br>treatment / all<br>deaths causally related to<br>treatment / all                                | 0 / 249 (0.00%)<br>0 / 0<br>0 / 0 | 1 / 250 (0.40%)<br>0 / 1<br>0 / 0 | 0 / 249 (0.00%)<br>0 / 0<br>0 / 0 |
| Blood and lymphatic system disorders<br>Anaemia<br>alternative assessment type:<br>Systematic                                                                                                                                    |                                   |                                   |                                   |

|                                                 |                 |                 |                 |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 249 (0.00%) | 1 / 250 (0.40%) | 0 / 249 (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           |
| Leukocytosis                                    |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 1 / 249 (0.40%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Splenomegaly                                    |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 1 / 249 (0.40%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Gastrointestinal disorders                      |                 |                 |                 |
| Diarrhoea                                       |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 2 / 249 (0.80%) | 2 / 250 (0.80%) | 4 / 249 (1.61%) |
| occurrences causally related to treatment / all | 0 / 2           | 0 / 2           | 0 / 4           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Dyspepsia                                       |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 1 / 249 (0.40%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Gastritis                                       |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 0 / 249 (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           |
| Gastrooesophageal reflux disease                |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |

|                                                 |                 |                 |                 |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 1 / 249 (0.40%) | 0 / 250 (0.00%) | 0 / 249 (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           |
| Inguinal hernia, obstructive                    |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 0 / 249 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Vomiting                                        |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 1 / 250 (0.40%) | 0 / 249 (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           |
| Hepatobiliary disorders                         |                 |                 |                 |
| Hepatitis                                       |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 1 / 249 (0.40%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Skin and subcutaneous tissue disorders          |                 |                 |                 |
| Urticaria                                       |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 1 / 249 (0.40%) | 0 / 250 (0.00%) | 0 / 249 (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           |
| Renal and urinary disorders                     |                 |                 |                 |
| Calculus urinary                                |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 0 / 249 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Hydronephrosis                                  |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |

|                                                 |                 |                 |                 |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 249 (0.00%) | 1 / 250 (0.40%) | 0 / 249 (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           |
| Hypercalciuria                                  |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 0 / 249 (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 tubular disorder                          |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 0 / 249 (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                     |                 |                 |                 |
| Bronchitis                                      |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 4 / 249 (1.61%) | 9 / 250 (3.60%) | 5 / 249 (2.01%) |
| occurrences causally related to treatment / all | 0 / 4           | 1 / 9           | 0 / 5           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Bronchopneumonia                                |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 3 / 250 (1.20%) | 0 / 249 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 3           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Gastroenteritis                                 |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 2 / 249 (0.80%) | 1 / 250 (0.40%) | 4 / 249 (1.61%) |
| occurrences causally related to treatment / all | 0 / 2           | 0 / 1           | 0 / 4           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Gastroenteritis rotavirus                       |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |

|                                                                        |                 |                 |                 |
|------------------------------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed                                            | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 0 / 249 (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           |
| Infectious mononucleosis<br>alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                                            | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 1 / 249 (0.40%) |
| occurrences causally related to treatment / all                        | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all                             | 0 / 0           | 0 / 0           | 0 / 0           |
| Laryngitis<br>alternative assessment type:<br>Systematic               |                 |                 |                 |
| subjects affected / exposed                                            | 1 / 249 (0.40%) | 0 / 250 (0.00%) | 1 / 249 (0.40%) |
| occurrences causally related to treatment / all                        | 0 / 1           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all                             | 0 / 0           | 0 / 0           | 0 / 0           |
| Meningitis meningococcal<br>alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                                            | 0 / 249 (0.00%) | 1 / 250 (0.40%) | 0 / 249 (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           |
| Meningococcal sepsis<br>alternative assessment type:<br>Systematic     |                 |                 |                 |
| subjects affected / exposed                                            | 0 / 249 (0.00%) | 1 / 250 (0.40%) | 0 / 249 (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           |
| Nasopharyngitis<br>alternative assessment type:<br>Systematic          |                 |                 |                 |
| subjects affected / exposed                                            | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 1 / 249 (0.40%) |
| occurrences causally related to treatment / all                        | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all                             | 0 / 0           | 0 / 0           | 0 / 0           |
| Otitis media<br>alternative assessment type:<br>Systematic             |                 |                 |                 |
| subjects affected / exposed                                            | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 1 / 249 (0.40%) |
| occurrences causally related to treatment / all                        | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all                             | 0 / 0           | 0 / 0           | 0 / 0           |

|                                                    |                 |                 |                 |  |
|----------------------------------------------------|-----------------|-----------------|-----------------|--|
| Pharyngitis                                        |                 |                 |                 |  |
| alternative assessment type:<br>Systematic         |                 |                 |                 |  |
| subjects affected / exposed                        | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 2 / 249 (0.80%) |  |
| occurrences causally related to<br>treatment / all | 0 / 0           | 0 / 0           | 0 / 2           |  |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |  |
| Pneumonia                                          |                 |                 |                 |  |
| alternative assessment type:<br>Systematic         |                 |                 |                 |  |
| subjects affected / exposed                        | 8 / 249 (3.21%) | 3 / 250 (1.20%) | 6 / 249 (2.41%) |  |
| occurrences causally related to<br>treatment / all | 0 / 8           | 0 / 3           | 0 / 6           |  |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |  |
| Pneumonia primary atypical                         |                 |                 |                 |  |
| alternative assessment type:<br>Systematic         |                 |                 |                 |  |
| subjects affected / exposed                        | 0 / 249 (0.00%) | 1 / 250 (0.40%) | 0 / 249 (0.00%) |  |
| occurrences causally related to<br>treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |  |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |  |
| Respiratory tract infection                        |                 |                 |                 |  |
| alternative assessment type:<br>Systematic         |                 |                 |                 |  |
| subjects affected / exposed                        | 1 / 249 (0.40%) | 1 / 250 (0.40%) | 0 / 249 (0.00%) |  |
| occurrences causally related to<br>treatment / all | 0 / 1           | 0 / 1           | 0 / 0           |  |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |  |
| Rhinitis                                           |                 |                 |                 |  |
| alternative assessment type:<br>Systematic         |                 |                 |                 |  |
| subjects affected / exposed                        | 0 / 249 (0.00%) | 2 / 250 (0.80%) | 0 / 249 (0.00%) |  |
| occurrences causally related to<br>treatment / all | 0 / 0           | 0 / 2           | 0 / 0           |  |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |  |
| Sepsis                                             |                 |                 |                 |  |
| alternative assessment type:<br>Systematic         |                 |                 |                 |  |
| subjects affected / exposed                        | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 0 / 249 (0.00%) |  |
| occurrences causally related to<br>treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |  |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |  |
| Staphylococcal bacteraemia                         |                 |                 |                 |  |
| alternative assessment type:<br>Systematic         |                 |                 |                 |  |

|                                                 |                 |                 |                 |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 1 / 249 (0.40%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Urinary tract infection                         |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 1 / 250 (0.40%) | 1 / 249 (0.40%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Viral infection                                 |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 2 / 249 (0.80%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 2           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Metabolism and nutrition disorders              |                 |                 |                 |
| Dehydration                                     |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 1 / 249 (0.40%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |

| <b>Serious adverse events</b>                                       | 13vPnC - P80 Post-Infant Series | 13vPnC - P80 Toddler Dose | 13vPnC + P80 Toddler Dose |
|---------------------------------------------------------------------|---------------------------------|---------------------------|---------------------------|
| Total subjects affected by serious adverse events                   |                                 |                           |                           |
| subjects affected / exposed                                         | 16 / 250 (6.40%)                | 2 / 244 (0.82%)           | 3 / 239 (1.26%)           |
| number of deaths (all causes)                                       | 0                               | 0                         | 0                         |
| number of deaths resulting from adverse events                      | 0                               | 0                         | 0                         |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                                 |                           |                           |
| Renal neoplasm                                                      |                                 |                           |                           |
| alternative assessment type: Systematic                             |                                 |                           |                           |
| subjects affected / exposed                                         | 0 / 250 (0.00%)                 | 0 / 244 (0.00%)           | 0 / 239 (0.00%)           |
| occurrences causally related to treatment / all                     | 0 / 0                           | 0 / 0                     | 0 / 0                     |
| deaths causally related to treatment / all                          | 0 / 0                           | 0 / 0                     | 0 / 0                     |
| General disorders and administration site conditions                |                                 |                           |                           |
| Fibrosis                                                            |                                 |                           |                           |
| alternative assessment type: Systematic                             |                                 |                           |                           |

|                                                 |                 |                 |                 |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 1 / 239 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Pyrexia                                         |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 1 / 250 (0.40%) | 0 / 244 (0.00%) | 0 / 239 (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           |
| Immune system disorders                         |                 |                 |                 |
| Alloimmunisation                                |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (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           |
| Hypersensitivity                                |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (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 |                 |                 |                 |
| Bronchospasm                                    |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 1 / 250 (0.40%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Pneumonia aspiration                            |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (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           |
| Sleep apnoea syndrome                           |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |

|                                                 |                 |                 |                 |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Psychiatric disorders                           |                 |                 |                 |
| Breath holding                                  |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Investigations                                  |                 |                 |                 |
| Ultrasound kidney abnormal                      |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 1 / 250 (0.40%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Injury, poisoning and procedural complications  |                 |                 |                 |
| Head injury                                     |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (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           |
| Limbic traumatic amputation                     |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 1 / 250 (0.40%) | 0 / 244 (0.00%) | 0 / 239 (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           |
| Radius fracture                                 |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Thermal burn                                    |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |

|                                                 |                 |                 |                 |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (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                        |                 |                 |                 |
| Balance disorder                                |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (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           |
| Febrile convulsion                              |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (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           |
| Hydrocephalus                                   |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Blood and lymphatic system disorders            |                 |                 |                 |
| Anaemia                                         |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (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           |
| Leukocytosis                                    |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (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           |
| Splenomegaly                                    |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |

|                                                 |                 |                 |                 |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Gastrointestinal disorders                      |                 |                 |                 |
| Diarrhoea                                       |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 3 / 250 (1.20%) | 0 / 244 (0.00%) | 1 / 239 (0.42%) |
| occurrences causally related to treatment / all | 0 / 3           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Dyspepsia                                       |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (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           |
| Gastritis                                       |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 250 (0.00%) | 1 / 244 (0.41%) | 0 / 239 (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           |
| Gastrooesophageal reflux disease                |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (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           |
| Inguinal hernia, obstructive                    |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 1 / 250 (0.40%) | 0 / 244 (0.00%) | 0 / 239 (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           |
| Vomiting                                        |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |

|                                                 |                 |                 |                 |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Hepatobiliary disorders                         |                 |                 |                 |
| Hepatitis                                       |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Skin and subcutaneous tissue disorders          |                 |                 |                 |
| Urticaria                                       |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 1 / 250 (0.40%) | 0 / 244 (0.00%) | 0 / 239 (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           |
| Renal and urinary disorders                     |                 |                 |                 |
| Calculus urinary                                |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Hydronephrosis                                  |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (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           |
| Hypercalciuria                                  |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 1 / 250 (0.40%) | 0 / 244 (0.00%) | 0 / 239 (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           |
| Renal tubular disorder                          |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |

|                                                 |                 |                 |                 |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 1 / 250 (0.40%) | 0 / 244 (0.00%) | 0 / 239 (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                     |                 |                 |                 |
| Bronchitis                                      |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 1 / 250 (0.40%) | 1 / 244 (0.41%) | 0 / 239 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Bronchopneumonia                                |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (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                                 |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 3 / 250 (1.20%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Gastroenteritis rotavirus                       |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (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           |
| Infectious mononucleosis                        |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (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           |
| Laryngitis                                      |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |

|                                                 |                 |                 |                 |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 2 / 250 (0.80%) | 0 / 244 (0.00%) | 1 / 239 (0.42%) |
| occurrences causally related to treatment / all | 0 / 2           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Meningitis meningococcal                        |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Meningococcal sepsis                            |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (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           |
| Nasopharyngitis                                 |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 1 / 250 (0.40%) | 0 / 244 (0.00%) | 0 / 239 (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           |
| Otitis media                                    |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Pharyngitis                                     |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 1 / 250 (0.40%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Pneumonia                                       |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 1 / 250 (0.40%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |

|                                                                           |                 |                 |                 |
|---------------------------------------------------------------------------|-----------------|-----------------|-----------------|
| Pneumonia primary atypical<br>alternative assessment type:<br>Systematic  |                 |                 |                 |
| subjects affected / exposed                                               | 1 / 250 (0.40%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences causally related to<br>treatment / all                        | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to<br>treatment / all                             | 0 / 0           | 0 / 0           | 0 / 0           |
| Respiratory tract infection<br>alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                                               | 1 / 250 (0.40%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences causally related to<br>treatment / all                        | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to<br>treatment / all                             | 0 / 0           | 0 / 0           | 0 / 0           |
| Rhinitis<br>alternative assessment type:<br>Systematic                    |                 |                 |                 |
| subjects affected / exposed                                               | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences causally related to<br>treatment / all                        | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to<br>treatment / all                             | 0 / 0           | 0 / 0           | 0 / 0           |
| Sepsis<br>alternative assessment type:<br>Systematic                      |                 |                 |                 |
| subjects affected / exposed                                               | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences causally related to<br>treatment / all                        | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to<br>treatment / all                             | 0 / 0           | 0 / 0           | 0 / 0           |
| Staphylococcal bacteraemia<br>alternative assessment type:<br>Systematic  |                 |                 |                 |
| subjects affected / exposed                                               | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences causally related to<br>treatment / all                        | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to<br>treatment / all                             | 0 / 0           | 0 / 0           | 0 / 0           |
| Urinary tract infection<br>alternative assessment type:<br>Systematic     |                 |                 |                 |
| subjects affected / exposed                                               | 2 / 250 (0.80%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences causally related to<br>treatment / all                        | 0 / 2           | 0 / 0           | 0 / 0           |
| deaths causally related to<br>treatment / all                             | 0 / 0           | 0 / 0           | 0 / 0           |
| Viral infection<br>alternative assessment type:<br>Systematic             |                 |                 |                 |

|                                                 |                 |                 |                 |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Metabolism and nutrition disorders              |                 |                 |                 |
| Dehydration                                     |                 |                 |                 |
| alternative assessment type: Systematic         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (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           |

| <b>Serious adverse events</b>                                       | 13vPnC + P80 6-Month Follow-up | 13vPnC - P80 6-Month Follow-up |  |
|---------------------------------------------------------------------|--------------------------------|--------------------------------|--|
| Total subjects affected by serious adverse events                   |                                |                                |  |
| subjects affected / exposed                                         | 13 / 249 (5.22%)               | 14 / 250 (5.60%)               |  |
| number of deaths (all causes)                                       | 0                              | 0                              |  |
| number of deaths resulting from adverse events                      | 0                              | 0                              |  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                                |                                |  |
| Renal neoplasm                                                      |                                |                                |  |
| alternative assessment type: Systematic                             |                                |                                |  |
| subjects affected / exposed                                         | 1 / 249 (0.40%)                | 0 / 250 (0.00%)                |  |
| occurrences causally related to treatment / all                     | 0 / 1                          | 0 / 0                          |  |
| deaths causally related to treatment / all                          | 0 / 0                          | 0 / 0                          |  |
| General disorders and administration site conditions                |                                |                                |  |
| Fibrosis                                                            |                                |                                |  |
| alternative assessment type: Systematic                             |                                |                                |  |
| subjects affected / exposed                                         | 0 / 249 (0.00%)                | 0 / 250 (0.00%)                |  |
| occurrences causally related to treatment / all                     | 0 / 0                          | 0 / 0                          |  |
| deaths causally related to treatment / all                          | 0 / 0                          | 0 / 0                          |  |
| Pyrexia                                                             |                                |                                |  |
| alternative assessment type: Systematic                             |                                |                                |  |
| subjects affected / exposed                                         | 0 / 249 (0.00%)                | 0 / 250 (0.00%)                |  |
| occurrences causally related to treatment / all                     | 0 / 0                          | 0 / 0                          |  |
| deaths causally related to treatment / all                          | 0 / 0                          | 0 / 0                          |  |
| Immune system disorders                                             |                                |                                |  |
| Alloimmunisation                                                    |                                |                                |  |

|                                                    |                 |                 |  |
|----------------------------------------------------|-----------------|-----------------|--|
| alternative assessment type:<br>Systematic         |                 |                 |  |
| subjects affected / exposed                        | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to<br>treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           |  |
| Hypersensitivity                                   |                 |                 |  |
| alternative assessment type:<br>Systematic         |                 |                 |  |
| subjects affected / exposed                        | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to<br>treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           |  |
| Respiratory, thoracic and mediastinal<br>disorders |                 |                 |  |
| Bronchospasm                                       |                 |                 |  |
| alternative assessment type:<br>Systematic         |                 |                 |  |
| subjects affected / exposed                        | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to<br>treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           |  |
| Pneumonia aspiration                               |                 |                 |  |
| alternative assessment type:<br>Systematic         |                 |                 |  |
| subjects affected / exposed                        | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to<br>treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           |  |
| Sleep apnoea syndrome                              |                 |                 |  |
| alternative assessment type:<br>Systematic         |                 |                 |  |
| subjects affected / exposed                        | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to<br>treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           |  |
| Psychiatric disorders                              |                 |                 |  |
| Breath holding                                     |                 |                 |  |
| alternative assessment type:<br>Systematic         |                 |                 |  |
| subjects affected / exposed                        | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to<br>treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           |  |
| Investigations                                     |                 |                 |  |
| Ultrasound kidney abnormal                         |                 |                 |  |

|                                                    |                 |                 |  |
|----------------------------------------------------|-----------------|-----------------|--|
| alternative assessment type:<br>Systematic         |                 |                 |  |
| subjects affected / exposed                        | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to<br>treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           |  |
| Injury, poisoning and procedural<br>complications  |                 |                 |  |
| Head injury                                        |                 |                 |  |
| alternative assessment type:<br>Systematic         |                 |                 |  |
| subjects affected / exposed                        | 1 / 249 (0.40%) | 0 / 250 (0.00%) |  |
| occurrences causally related to<br>treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           |  |
| Limbic traumatic amputation                        |                 |                 |  |
| alternative assessment type:<br>Systematic         |                 |                 |  |
| subjects affected / exposed                        | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to<br>treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           |  |
| Radius fracture                                    |                 |                 |  |
| alternative assessment type:<br>Systematic         |                 |                 |  |
| subjects affected / exposed                        | 1 / 249 (0.40%) | 0 / 250 (0.00%) |  |
| occurrences causally related to<br>treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           |  |
| Thermal burn                                       |                 |                 |  |
| alternative assessment type:<br>Systematic         |                 |                 |  |
| subjects affected / exposed                        | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to<br>treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           |  |
| Nervous system disorders                           |                 |                 |  |
| Balance disorder                                   |                 |                 |  |
| alternative assessment type:<br>Systematic         |                 |                 |  |
| subjects affected / exposed                        | 0 / 249 (0.00%) | 1 / 250 (0.40%) |  |
| occurrences causally related to<br>treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           |  |
| Febrile convulsion                                 |                 |                 |  |
| alternative assessment type:<br>Systematic         |                 |                 |  |

|                                                 |                 |                 |  |
|-------------------------------------------------|-----------------|-----------------|--|
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Hydrocephalus                                   |                 |                 |  |
| alternative assessment type: Systematic         |                 |                 |  |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 1 / 250 (0.40%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Blood and lymphatic system disorders            |                 |                 |  |
| Anaemia                                         |                 |                 |  |
| alternative assessment type: Systematic         |                 |                 |  |
| subjects affected / exposed                     | 1 / 249 (0.40%) | 0 / 250 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Leukocytosis                                    |                 |                 |  |
| alternative assessment type: Systematic         |                 |                 |  |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Splenomegaly                                    |                 |                 |  |
| alternative assessment type: Systematic         |                 |                 |  |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Gastrointestinal disorders                      |                 |                 |  |
| Diarrhoea                                       |                 |                 |  |
| alternative assessment type: Systematic         |                 |                 |  |
| subjects affected / exposed                     | 3 / 249 (1.20%) | 4 / 250 (1.60%) |  |
| occurrences causally related to treatment / all | 0 / 3           | 0 / 4           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Dyspepsia                                       |                 |                 |  |
| alternative assessment type: Systematic         |                 |                 |  |

|                                                 |                 |                 |  |
|-------------------------------------------------|-----------------|-----------------|--|
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Gastritis                                       |                 |                 |  |
| alternative assessment type: Systematic         |                 |                 |  |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Gastrooesophageal reflux disease                |                 |                 |  |
| alternative assessment type: Systematic         |                 |                 |  |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Inguinal hernia, obstructive                    |                 |                 |  |
| alternative assessment type: Systematic         |                 |                 |  |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Vomiting                                        |                 |                 |  |
| alternative assessment type: Systematic         |                 |                 |  |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Hepatobiliary disorders                         |                 |                 |  |
| Hepatitis                                       |                 |                 |  |
| alternative assessment type: Systematic         |                 |                 |  |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Skin and subcutaneous tissue disorders          |                 |                 |  |
| Urticaria                                       |                 |                 |  |
| alternative assessment type: Systematic         |                 |                 |  |

|                                                 |                 |                 |  |
|-------------------------------------------------|-----------------|-----------------|--|
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Renal and urinary disorders                     |                 |                 |  |
| Calculus urinary                                |                 |                 |  |
| alternative assessment type: Systematic         |                 |                 |  |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 1 / 250 (0.40%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Hydronephrosis                                  |                 |                 |  |
| alternative assessment type: Systematic         |                 |                 |  |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Hypercalciuria                                  |                 |                 |  |
| alternative assessment type: Systematic         |                 |                 |  |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Renal tubular disorder                          |                 |                 |  |
| alternative assessment type: Systematic         |                 |                 |  |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 1 / 250 (0.40%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 2           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Infections and infestations                     |                 |                 |  |
| Bronchitis                                      |                 |                 |  |
| alternative assessment type: Systematic         |                 |                 |  |
| subjects affected / exposed                     | 1 / 249 (0.40%) | 2 / 250 (0.80%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 2           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Bronchopneumonia                                |                 |                 |  |
| alternative assessment type: Systematic         |                 |                 |  |

|                                                 |                 |                 |  |  |
|-------------------------------------------------|-----------------|-----------------|--|--|
| subjects affected / exposed                     | 1 / 249 (0.40%) | 0 / 250 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |  |
| Gastroenteritis                                 |                 |                 |  |  |
| alternative assessment type: Systematic         |                 |                 |  |  |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 1 / 250 (0.40%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |  |
| Gastroenteritis rotavirus                       |                 |                 |  |  |
| alternative assessment type: Systematic         |                 |                 |  |  |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 1 / 250 (0.40%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |  |
| Infectious mononucleosis                        |                 |                 |  |  |
| alternative assessment type: Systematic         |                 |                 |  |  |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |  |
| Laryngitis                                      |                 |                 |  |  |
| alternative assessment type: Systematic         |                 |                 |  |  |
| subjects affected / exposed                     | 3 / 249 (1.20%) | 0 / 250 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 3           | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |  |
| Meningitis meningococcal                        |                 |                 |  |  |
| alternative assessment type: Systematic         |                 |                 |  |  |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |  |
| Meningococcal sepsis                            |                 |                 |  |  |
| alternative assessment type: Systematic         |                 |                 |  |  |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |  |

|                                                    |                 |                 |  |
|----------------------------------------------------|-----------------|-----------------|--|
| Nasopharyngitis                                    |                 |                 |  |
| alternative assessment type:<br>Systematic         |                 |                 |  |
| subjects affected / exposed                        | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to<br>treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           |  |
| Otitis media                                       |                 |                 |  |
| alternative assessment type:<br>Systematic         |                 |                 |  |
| subjects affected / exposed                        | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to<br>treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           |  |
| Pharyngitis                                        |                 |                 |  |
| alternative assessment type:<br>Systematic         |                 |                 |  |
| subjects affected / exposed                        | 2 / 249 (0.80%) | 0 / 250 (0.00%) |  |
| occurrences causally related to<br>treatment / all | 0 / 2           | 0 / 0           |  |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           |  |
| Pneumonia                                          |                 |                 |  |
| alternative assessment type:<br>Systematic         |                 |                 |  |
| subjects affected / exposed                        | 3 / 249 (1.20%) | 3 / 250 (1.20%) |  |
| occurrences causally related to<br>treatment / all | 0 / 3           | 0 / 3           |  |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           |  |
| Pneumonia primary atypical                         |                 |                 |  |
| alternative assessment type:<br>Systematic         |                 |                 |  |
| subjects affected / exposed                        | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to<br>treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           |  |
| Respiratory tract infection                        |                 |                 |  |
| alternative assessment type:<br>Systematic         |                 |                 |  |
| subjects affected / exposed                        | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to<br>treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           |  |
| Rhinitis                                           |                 |                 |  |
| alternative assessment type:<br>Systematic         |                 |                 |  |

|                                                 |                 |                 |  |
|-------------------------------------------------|-----------------|-----------------|--|
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Sepsis                                          |                 |                 |  |
| alternative assessment type: Systematic         |                 |                 |  |
| subjects affected / exposed                     | 1 / 249 (0.40%) | 0 / 250 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Staphylococcal bacteraemia                      |                 |                 |  |
| alternative assessment type: Systematic         |                 |                 |  |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Urinary tract infection                         |                 |                 |  |
| alternative assessment type: Systematic         |                 |                 |  |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 1 / 250 (0.40%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Viral infection                                 |                 |                 |  |
| alternative assessment type: Systematic         |                 |                 |  |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Metabolism and nutrition disorders              |                 |                 |  |
| Dehydration                                     |                 |                 |  |
| alternative assessment type: Systematic         |                 |                 |  |
| subjects affected / exposed                     | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |

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

| Non-serious adverse events                                      | 13vPnC + P80<br>Infant Series                                                                                                                                                                                                                                                             | 13vPnC - P 80 Infant<br>Series | 13vPnC + P80 Post-<br>Infant Series |
|-----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|-------------------------------------|
| Total subjects affected by non-serious<br>adverse events        |                                                                                                                                                                                                                                                                                           |                                |                                     |
| subjects affected / exposed                                     | 132 / 249 (53.01%)                                                                                                                                                                                                                                                                        | 132 / 250 (52.80%)             | 15 / 249 (6.02%)                    |
| General disorders and administration<br>site conditions         |                                                                                                                                                                                                                                                                                           |                                |                                     |
| Pyrexia                                                         |                                                                                                                                                                                                                                                                                           |                                |                                     |
| alternative assessment type:<br>Systematic                      |                                                                                                                                                                                                                                                                                           |                                |                                     |
| subjects affected / exposed                                     | 5 / 249 (2.01%)                                                                                                                                                                                                                                                                           | 4 / 250 (1.60%)                | 0 / 249 (0.00%)                     |
| occurrences (all)                                               | 5                                                                                                                                                                                                                                                                                         | 4                              | 0                                   |
| Irritability                                                    |                                                                                                                                                                                                                                                                                           |                                |                                     |
| alternative assessment type:<br>Systematic                      |                                                                                                                                                                                                                                                                                           |                                |                                     |
| subjects affected / exposed                                     | 1 / 249 (0.40%)                                                                                                                                                                                                                                                                           | 1 / 250 (0.40%)                | 0 / 249 (0.00%)                     |
| occurrences (all)                                               | 1                                                                                                                                                                                                                                                                                         | 1                              | 0                                   |
| Injection site induration                                       |                                                                                                                                                                                                                                                                                           |                                |                                     |
| alternative assessment type:<br>Systematic                      |                                                                                                                                                                                                                                                                                           |                                |                                     |
| subjects affected / exposed                                     | 1 / 249 (0.40%)                                                                                                                                                                                                                                                                           | 0 / 250 (0.00%)                | 0 / 249 (0.00%)                     |
| occurrences (all)                                               | 2                                                                                                                                                                                                                                                                                         | 0                              | 0                                   |
| Injection site nodule                                           |                                                                                                                                                                                                                                                                                           |                                |                                     |
| alternative assessment type:<br>Systematic                      |                                                                                                                                                                                                                                                                                           |                                |                                     |
| subjects affected / exposed                                     | 1 / 249 (0.40%)                                                                                                                                                                                                                                                                           | 0 / 250 (0.00%)                | 0 / 249 (0.00%)                     |
| occurrences (all)                                               | 2                                                                                                                                                                                                                                                                                         | 0                              | 0                                   |
| Injection site swelling                                         |                                                                                                                                                                                                                                                                                           |                                |                                     |
| alternative assessment type:<br>Systematic                      |                                                                                                                                                                                                                                                                                           |                                |                                     |
| subjects affected / exposed                                     | 0 / 249 (0.00%)                                                                                                                                                                                                                                                                           | 1 / 250 (0.40%)                | 0 / 249 (0.00%)                     |
| occurrences (all)                                               | 0                                                                                                                                                                                                                                                                                         | 1                              | 0                                   |
| Fever ≥38°C but ≤39°C: Infant<br>Series Dose 1 and Toddler Dose | Additional description: Subjects affected and occurrences for LRs and SEs is<br>same as data collected through e-diaries cannot be used to distinguish one<br>occurrence from another within a subject/vaccination.Version not captured, here<br>0.0 is mentioned for dictionary version. |                                |                                     |
| alternative dictionary used:<br>Systemic Events 0.0             |                                                                                                                                                                                                                                                                                           |                                |                                     |
| alternative assessment type:<br>Systematic                      |                                                                                                                                                                                                                                                                                           |                                |                                     |
| subjects affected / exposed <sup>[1]</sup>                      | 33 / 236 (13.98%)                                                                                                                                                                                                                                                                         | 38 / 235 (16.17%)              | 0 / 1 (0.00%)                       |
| occurrences (all)                                               | 33                                                                                                                                                                                                                                                                                        | 38                             | 0                                   |
| Fever ≥38°C but ≤39°C: Infant<br>Series Dose 2                  | Additional description: Subjects affected and occurrences for LRs and SEs is<br>same as data collected through e-diaries cannot be used to distinguish one<br>occurrence from another within a subject/vaccination.Version not captured, here<br>0.0 is mentioned for dictionary version. |                                |                                     |
| alternative dictionary used:<br>Systemic Events 0.0             |                                                                                                                                                                                                                                                                                           |                                |                                     |
| alternative assessment type:<br>Systematic                      |                                                                                                                                                                                                                                                                                           |                                |                                     |

|                                                                                                                                                                      |                                                                                                                                                                                                                                                                                   |                         |                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|
| subjects affected / exposed <sup>[2]</sup><br>occurrences (all)                                                                                                      | 41 / 224 (18.30%)<br>41                                                                                                                                                                                                                                                           | 39 / 229 (17.03%)<br>39 | 0 / 1 (0.00%)<br>0 |
| Fever ≥38°C but ≤39°C: Infant Series Dose 3                                                                                                                          | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                         |                    |
| alternative dictionary used:<br>Systemic Events 0.0<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed <sup>[3]</sup><br>occurrences (all) | 41 / 208 (19.71%)<br>41                                                                                                                                                                                                                                                           | 45 / 218 (20.64%)<br>45 | 0 / 1 (0.00%)<br>0 |
| Fever >39°C but ≤40°C: Infant Series Dose 1 and Toddler Dose                                                                                                         | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                         |                    |
| alternative dictionary used:<br>Systemic Events 0.0<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed <sup>[4]</sup><br>occurrences (all) | 1 / 235 (0.43%)<br>1                                                                                                                                                                                                                                                              | 1 / 233 (0.43%)<br>1    | 0 / 1 (0.00%)<br>0 |
| Fever >39°C but ≤40°C: Infant Series Dose 2                                                                                                                          | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                         |                    |
| alternative dictionary used:<br>Systemic Events 0.0<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed <sup>[5]</sup><br>occurrences (all) | 2 / 221 (0.90%)<br>2                                                                                                                                                                                                                                                              | 1 / 221 (0.45%)<br>1    | 0 / 1 (0.00%)<br>0 |
| Fever >39°C but ≤40°C: Infant Series Dose 3                                                                                                                          | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                         |                    |
| alternative dictionary used:<br>Systemic Events 0.0<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed <sup>[6]</sup><br>occurrences (all) | 2 / 203 (0.99%)<br>2                                                                                                                                                                                                                                                              | 2 / 211 (0.95%)<br>2    | 0 / 1 (0.00%)<br>0 |
| Decreased appetite: Infant Series Dose 1 and Toddler Dose                                                                                                            | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                         |                    |
| alternative dictionary used:<br>Systemic Events 0.0<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed <sup>[7]</sup><br>occurrences (all) | 51 / 237 (21.52%)<br>51                                                                                                                                                                                                                                                           | 53 / 237 (22.36%)<br>53 | 0 / 1 (0.00%)<br>0 |
| Decreased appetite: Infant Series Dose 2                                                                                                                             | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                         |                    |

|                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                         |                                    |                               |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|-------------------------------|
| <p>alternative dictionary used:<br/>Systemic Events 0.0</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[8]</sup></p> <p>occurrences (all)</p>  | <p>36 / 221 (16.29%)</p> <p>36</p>                                                                                                                                                                                                                                                      | <p>54 / 224 (24.11%)</p> <p>54</p> | <p>0 / 1 (0.00%)</p> <p>0</p> |
| Decreased appetite: Infant Series Dose 3                                                                                                                                                  | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                                    |                               |
| <p>alternative dictionary used:<br/>Systemic Events 0.0</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[9]</sup></p> <p>occurrences (all)</p>  | <p>45 / 210 (21.43%)</p> <p>45</p>                                                                                                                                                                                                                                                      | <p>46 / 222 (20.72%)</p> <p>46</p> | <p>0 / 1 (0.00%)</p> <p>0</p> |
| Decreased sleep: Infant Series Dose 1 and Toddler Dose                                                                                                                                    | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                                    |                               |
| <p>alternative dictionary used:<br/>Systemic Events 0.0</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[10]</sup></p> <p>occurrences (all)</p> | <p>85 / 238 (35.71%)</p> <p>85</p>                                                                                                                                                                                                                                                      | <p>70 / 236 (29.66%)</p> <p>70</p> | <p>0 / 1 (0.00%)</p> <p>0</p> |
| Decreased sleep: Infant Series Dose 2                                                                                                                                                     | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                                    |                               |
| <p>alternative dictionary used:<br/>Systemic Events 0.0</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[11]</sup></p> <p>occurrences (all)</p> | <p>56 / 227 (24.67%)</p> <p>56</p>                                                                                                                                                                                                                                                      | <p>60 / 227 (26.43%)</p> <p>60</p> | <p>0 / 1 (0.00%)</p> <p>0</p> |
| Decreased sleep: Infant Series Dose 3                                                                                                                                                     | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                                    |                               |
| <p>alternative dictionary used:<br/>Systemic Events 0.0</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[12]</sup></p> <p>occurrences (all)</p> | <p>53 / 209 (25.36%)</p> <p>53</p>                                                                                                                                                                                                                                                      | <p>53 / 217 (24.42%)</p> <p>53</p> | <p>0 / 1 (0.00%)</p> <p>0</p> |
| Increased sleep: Infant Series Dose 1 and Toddler Dose                                                                                                                                    | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                                    |                               |
| <p>alternative dictionary used:<br/>Systemic Events 0.0</p> <p>alternative assessment type:<br/>Systematic</p>                                                                            |                                                                                                                                                                                                                                                                                         |                                    |                               |

|                                                     |                                                                                                                                                                                                                                                                                  |                    |               |
|-----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|---------------|
| subjects affected / exposed <sup>[13]</sup>         | 112 / 242 (46.28%)                                                                                                                                                                                                                                                               | 127 / 242 (52.48%) | 0 / 1 (0.00%) |
| occurrences (all)                                   | 112                                                                                                                                                                                                                                                                              | 127                | 0             |
| Increased sleep: Infant Series Dose 2               | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                    |               |
| alternative dictionary used:<br>Systemic Events 0.0 |                                                                                                                                                                                                                                                                                  |                    |               |
| alternative assessment type:<br>Systematic          |                                                                                                                                                                                                                                                                                  |                    |               |
| subjects affected / exposed <sup>[14]</sup>         | 83 / 231 (35.93%)                                                                                                                                                                                                                                                                | 90 / 229 (39.30%)  | 0 / 1 (0.00%) |
| occurrences (all)                                   | 83                                                                                                                                                                                                                                                                               | 90                 | 0             |
| Increased sleep: Infant Series Dose 3               | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                    |               |
| alternative dictionary used:<br>Systemic Events 0.0 |                                                                                                                                                                                                                                                                                  |                    |               |
| alternative assessment type:<br>Systematic          |                                                                                                                                                                                                                                                                                  |                    |               |
| subjects affected / exposed <sup>[15]</sup>         | 54 / 209 (25.84%)                                                                                                                                                                                                                                                                | 61 / 221 (27.60%)  | 0 / 1 (0.00%) |
| occurrences (all)                                   | 54                                                                                                                                                                                                                                                                               | 61                 | 0             |
| Irritability: Infant Series Dose 1 and Toddler Dose | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                    |               |
| alternative dictionary used:<br>Systemic Events 0.0 |                                                                                                                                                                                                                                                                                  |                    |               |
| alternative assessment type:<br>Systematic          |                                                                                                                                                                                                                                                                                  |                    |               |
| subjects affected / exposed <sup>[16]</sup>         | 132 / 240 (55.00%)                                                                                                                                                                                                                                                               | 132 / 239 (55.23%) | 0 / 1 (0.00%) |
| occurrences (all)                                   | 132                                                                                                                                                                                                                                                                              | 132                | 0             |
| Irritability: Infant Series Dose 2                  | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                    |               |
| alternative dictionary used:<br>Systemic Events 0.0 |                                                                                                                                                                                                                                                                                  |                    |               |
| alternative assessment type:<br>Systematic          |                                                                                                                                                                                                                                                                                  |                    |               |
| subjects affected / exposed <sup>[17]</sup>         | 120 / 232 (51.72%)                                                                                                                                                                                                                                                               | 125 / 232 (53.88%) | 0 / 1 (0.00%) |
| occurrences (all)                                   | 120                                                                                                                                                                                                                                                                              | 125                | 0             |
| Irritability: Infant Series Dose 3                  | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                    |               |
| alternative dictionary used:<br>Systemic Events 0.0 |                                                                                                                                                                                                                                                                                  |                    |               |
| alternative assessment type:<br>Systematic          |                                                                                                                                                                                                                                                                                  |                    |               |
| subjects affected / exposed <sup>[18]</sup>         | 98 / 215 (45.58%)                                                                                                                                                                                                                                                                | 113 / 226 (50.00%) | 0 / 1 (0.00%) |
| occurrences (all)                                   | 98                                                                                                                                                                                                                                                                               | 113                | 0             |
| Immune system disorders                             |                                                                                                                                                                                                                                                                                  |                    |               |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                          |                                                                                                          |                                                                                                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|
| Food allergy<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                                                                                                                                                                           | 0 / 249 (0.00%)<br>0                                                                                     | 3 / 250 (1.20%)<br>3                                                                                     | 0 / 249 (0.00%)<br>0                                                                                     |
| Respiratory, thoracic and mediastinal disorders<br>Cough<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Interstitial lung disease<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Pharyngolaryngeal pain<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Rhinitis allergic<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all) | 2 / 249 (0.80%)<br>2<br><br>1 / 249 (0.40%)<br>2<br><br>1 / 249 (0.40%)<br>1<br><br>1 / 249 (0.40%)<br>1 | 0 / 250 (0.00%)<br>0<br><br>0 / 250 (0.00%)<br>0<br><br>0 / 250 (0.00%)<br>0<br><br>0 / 250 (0.00%)<br>0 | 0 / 249 (0.00%)<br>0<br><br>0 / 249 (0.00%)<br>0<br><br>0 / 249 (0.00%)<br>0<br><br>1 / 249 (0.40%)<br>1 |
| Psychiatric disorders<br>Decreased activity<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Insomnia<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                          | 1 / 249 (0.40%)<br>1<br><br>0 / 249 (0.00%)<br>0                                                         | 0 / 250 (0.00%)<br>0<br><br>1 / 250 (0.40%)<br>1                                                         | 0 / 249 (0.00%)<br>0<br><br>0 / 249 (0.00%)<br>0                                                         |
| Investigations<br>Cardiac murmur functional<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                                                                                                                                            | 1 / 249 (0.40%)<br>1                                                                                     | 2 / 250 (0.80%)<br>2                                                                                     | 0 / 249 (0.00%)<br>0                                                                                     |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                  |                                                                                                                                      |                                                                                                                                      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|
| Cardiac murmur<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 0 / 249 (0.00%)<br>0                                                                                                                                             | 0 / 250 (0.00%)<br>0                                                                                                                 | 0 / 249 (0.00%)<br>0                                                                                                                 |
| Congenital, familial and genetic disorders<br>Craniotabes<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Dacryostenosis congenital<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Brachycephaly<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Cryptorchism<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Ventricular septal defect<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all) | 0 / 249 (0.00%)<br>0<br><br>0 / 249 (0.00%)<br>0<br><br>0 / 249 (0.00%)<br>0<br><br>0 / 249 (0.00%)<br>0<br><br>0 / 249 (0.00%)<br>0<br><br>0 / 249 (0.00%)<br>0 | 1 / 250 (0.40%)<br>1<br><br>1 / 250 (0.40%)<br>1<br><br>0 / 250 (0.00%)<br>0<br><br>0 / 250 (0.00%)<br>0<br><br>0 / 250 (0.00%)<br>0 | 0 / 249 (0.00%)<br>0<br><br>0 / 249 (0.00%)<br>0<br><br>0 / 249 (0.00%)<br>0<br><br>1 / 249 (0.40%)<br>1<br><br>0 / 249 (0.00%)<br>0 |
| Cardiac disorders<br>Aortic valve incompetence<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Tricuspid valve incompetence<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                                                                                                                         | 0 / 249 (0.00%)<br>0<br><br>0 / 249 (0.00%)<br>0                                                                                                                 | 0 / 250 (0.00%)<br>0<br><br>0 / 250 (0.00%)<br>0                                                                                     | 0 / 249 (0.00%)<br>0<br><br>0 / 249 (0.00%)<br>0                                                                                     |
| Nervous system disorders                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                  |                                                                                                                                      |                                                                                                                                      |

|                                                                                                                                                   |                      |                        |                      |
|---------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|------------------------|----------------------|
| Hypertonia<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                                      | 1 / 249 (0.40%)<br>1 | 3 / 250 (1.20%)<br>3   | 0 / 249 (0.00%)<br>0 |
| Hypotonia<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                                       | 2 / 249 (0.80%)<br>2 | 0 / 250 (0.00%)<br>0   | 0 / 249 (0.00%)<br>0 |
| Blood and lymphatic system disorders<br>Anaemia<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all) | 2 / 249 (0.80%)<br>2 | 2 / 250 (0.80%)<br>2   | 0 / 249 (0.00%)<br>0 |
| Iron deficiency anaemia<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                         | 0 / 249 (0.00%)<br>0 | 1 / 250 (0.40%)<br>1   | 0 / 249 (0.00%)<br>0 |
| Eye disorders<br>Conjunctivitis<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                 | 5 / 249 (2.01%)<br>5 | 2 / 250 (0.80%)<br>2   | 1 / 249 (0.40%)<br>1 |
| Gastrointestinal disorders<br>Diarrhoea<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)         | 5 / 249 (2.01%)<br>5 | 11 / 250 (4.40%)<br>12 | 0 / 249 (0.00%)<br>0 |
| Vomiting<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                                        | 2 / 249 (0.80%)<br>3 | 3 / 250 (1.20%)<br>4   | 0 / 249 (0.00%)<br>0 |
| Abdominal pain<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                                  | 1 / 249 (0.40%)<br>1 | 2 / 250 (0.80%)<br>2   | 0 / 249 (0.00%)<br>0 |
| Haematochezia                                                                                                                                     |                      |                        |                      |

|                                            |                 |                 |                 |
|--------------------------------------------|-----------------|-----------------|-----------------|
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 1 / 249 (0.40%) | 1 / 250 (0.40%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 1               | 1               | 0               |
| Abdominal distension                       |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 1 / 249 (0.40%) | 0 / 250 (0.00%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 1               | 0               | 0               |
| Aphthous stomatitis                        |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 249 (0.00%) | 1 / 250 (0.40%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 0               | 1               | 0               |
| Constipation                               |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 249 (0.00%) | 1 / 250 (0.40%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 0               | 2               | 0               |
| Dyspepsia                                  |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 1 / 249 (0.40%) | 0 / 250 (0.00%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 1               | 0               | 0               |
| Infantile colic                            |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 1 / 249 (0.40%) | 0 / 250 (0.00%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 1               | 0               | 0               |
| Umbilical hernia                           |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 1 / 249 (0.40%) | 0 / 250 (0.00%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 1               | 0               | 0               |
| Gastrooesophageal reflux disease           |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 2 / 249 (0.80%) |
| occurrences (all)                          | 0               | 0               | 2               |
| Stomatitis                                 |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |

|                                                  |                      |                      |                      |
|--------------------------------------------------|----------------------|----------------------|----------------------|
| subjects affected / exposed<br>occurrences (all) | 0 / 249 (0.00%)<br>0 | 0 / 250 (0.00%)<br>0 | 0 / 249 (0.00%)<br>0 |
| Skin and subcutaneous tissue disorders           |                      |                      |                      |
| Dermatitis atopic                                |                      |                      |                      |
| alternative assessment type:<br>Systematic       |                      |                      |                      |
| subjects affected / exposed                      | 14 / 249 (5.62%)     | 7 / 250 (2.80%)      | 3 / 249 (1.20%)      |
| occurrences (all)                                | 14                   | 7                    | 3                    |
| Dermatitis allergic                              |                      |                      |                      |
| alternative assessment type:<br>Systematic       |                      |                      |                      |
| subjects affected / exposed                      | 3 / 249 (1.20%)      | 8 / 250 (3.20%)      | 1 / 249 (0.40%)      |
| occurrences (all)                                | 4                    | 8                    | 1                    |
| Rash                                             |                      |                      |                      |
| alternative assessment type:<br>Systematic       |                      |                      |                      |
| subjects affected / exposed                      | 5 / 249 (2.01%)      | 1 / 250 (0.40%)      | 1 / 249 (0.40%)      |
| occurrences (all)                                | 5                    | 1                    | 1                    |
| Dermatitis                                       |                      |                      |                      |
| alternative assessment type:<br>Systematic       |                      |                      |                      |
| subjects affected / exposed                      | 1 / 249 (0.40%)      | 1 / 250 (0.40%)      | 0 / 249 (0.00%)      |
| occurrences (all)                                | 1                    | 1                    | 0                    |
| Dermatitis diaper                                |                      |                      |                      |
| alternative assessment type:<br>Systematic       |                      |                      |                      |
| subjects affected / exposed                      | 1 / 249 (0.40%)      | 1 / 250 (0.40%)      | 1 / 249 (0.40%)      |
| occurrences (all)                                | 1                    | 1                    | 1                    |
| Heat rash                                        |                      |                      |                      |
| alternative assessment type:<br>Systematic       |                      |                      |                      |
| subjects affected / exposed                      | 2 / 249 (0.80%)      | 0 / 250 (0.00%)      | 0 / 249 (0.00%)      |
| occurrences (all)                                | 2                    | 0                    | 0                    |
| Dermatitis contact                               |                      |                      |                      |
| alternative assessment type:<br>Systematic       |                      |                      |                      |
| subjects affected / exposed                      | 0 / 249 (0.00%)      | 1 / 250 (0.40%)      | 0 / 249 (0.00%)      |
| occurrences (all)                                | 0                    | 1                    | 0                    |
| Hyperhidrosis                                    |                      |                      |                      |
| alternative assessment type:<br>Systematic       |                      |                      |                      |

|                                                                    |                                                                                                                                                                                                                                                                                  |                   |                 |
|--------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|-----------------|
| subjects affected / exposed                                        | 1 / 249 (0.40%)                                                                                                                                                                                                                                                                  | 0 / 250 (0.00%)   | 0 / 249 (0.00%) |
| occurrences (all)                                                  | 1                                                                                                                                                                                                                                                                                | 0                 | 0               |
| Seborrhoeic dermatitis                                             |                                                                                                                                                                                                                                                                                  |                   |                 |
| alternative assessment type:<br>Systematic                         |                                                                                                                                                                                                                                                                                  |                   |                 |
| subjects affected / exposed                                        | 1 / 249 (0.40%)                                                                                                                                                                                                                                                                  | 0 / 250 (0.00%)   | 0 / 249 (0.00%) |
| occurrences (all)                                                  | 1                                                                                                                                                                                                                                                                                | 0                 | 0               |
| Skin inflammation                                                  |                                                                                                                                                                                                                                                                                  |                   |                 |
| alternative assessment type:<br>Systematic                         |                                                                                                                                                                                                                                                                                  |                   |                 |
| subjects affected / exposed                                        | 0 / 249 (0.00%)                                                                                                                                                                                                                                                                  | 1 / 250 (0.40%)   | 0 / 249 (0.00%) |
| occurrences (all)                                                  | 0                                                                                                                                                                                                                                                                                | 1                 | 0               |
| Urticaria                                                          |                                                                                                                                                                                                                                                                                  |                   |                 |
| alternative assessment type:<br>Systematic                         |                                                                                                                                                                                                                                                                                  |                   |                 |
| subjects affected / exposed                                        | 0 / 249 (0.00%)                                                                                                                                                                                                                                                                  | 1 / 250 (0.40%)   | 0 / 249 (0.00%) |
| occurrences (all)                                                  | 0                                                                                                                                                                                                                                                                                | 1                 | 0               |
| Tenderness (Any): Infant Series<br>Dose 1 and Toddler Dose         | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                   |                 |
| alternative dictionary used: Local<br>Reactions 0.0                |                                                                                                                                                                                                                                                                                  |                   |                 |
| alternative assessment type:<br>Systematic                         |                                                                                                                                                                                                                                                                                  |                   |                 |
| subjects affected / exposed <sup>[19]</sup>                        | 45 / 181 (24.86%)                                                                                                                                                                                                                                                                | 59 / 181 (32.60%) | 0 / 1 (0.00%)   |
| occurrences (all)                                                  | 45                                                                                                                                                                                                                                                                               | 59                | 0               |
| Tenderness (Any): Infant Series<br>Dose 2                          | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                   |                 |
| alternative dictionary used: Local<br>Reactions 0.0                |                                                                                                                                                                                                                                                                                  |                   |                 |
| alternative assessment type:<br>Systematic                         |                                                                                                                                                                                                                                                                                  |                   |                 |
| subjects affected / exposed <sup>[20]</sup>                        | 43 / 176 (24.43%)                                                                                                                                                                                                                                                                | 63 / 176 (35.80%) | 0 / 1 (0.00%)   |
| occurrences (all)                                                  | 43                                                                                                                                                                                                                                                                               | 63                | 0               |
| Tenderness (Any): Infant Series<br>Dose 3                          | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                   |                 |
| alternative dictionary used: Local<br>Reactions 0.0                |                                                                                                                                                                                                                                                                                  |                   |                 |
| alternative assessment type:<br>Systematic                         |                                                                                                                                                                                                                                                                                  |                   |                 |
| subjects affected / exposed <sup>[21]</sup>                        | 41 / 167 (24.55%)                                                                                                                                                                                                                                                                | 38 / 170 (22.35%) | 0 / 1 (0.00%)   |
| occurrences (all)                                                  | 41                                                                                                                                                                                                                                                                               | 38                | 0               |
| Tenderness (significant): Infant<br>Series Dose 1 and Toddler Dose | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                   |                 |

|                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                         |                                    |                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|-------------------------------|
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[22]</sup></p> <p>occurrences (all)</p> | <p>4 / 179 (2.23%)</p> <p>4</p>                                                                                                                                                                                                                                                         | <p>8 / 178 (4.49%)</p> <p>8</p>    | <p>0 / 1 (0.00%)</p> <p>0</p> |
| <p>Tenderness (significant): Infant Series Dose 2</p>                                                                                                                             | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                                    |                               |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[23]</sup></p> <p>occurrences (all)</p> | <p>1 / 172 (0.58%)</p> <p>1</p>                                                                                                                                                                                                                                                         | <p>1 / 170 (0.59%)</p> <p>1</p>    | <p>0 / 1 (0.00%)</p> <p>0</p> |
| <p>Tenderness (significant): Infant Series Dose 3</p>                                                                                                                             | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                                    |                               |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[24]</sup></p> <p>occurrences (all)</p> | <p>2 / 163 (1.23%)</p> <p>2</p>                                                                                                                                                                                                                                                         | <p>2 / 165 (1.21%)</p> <p>2</p>    | <p>0 / 1 (0.00%)</p> <p>0</p> |
| <p>Induration (Any): Infant Series Dose 1 and Toddler Dose</p>                                                                                                                    | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                                    |                               |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[25]</sup></p> <p>occurrences (all)</p> | <p>39 / 179 (21.79%)</p> <p>39</p>                                                                                                                                                                                                                                                      | <p>55 / 183 (30.05%)</p> <p>55</p> | <p>0 / 1 (0.00%)</p> <p>0</p> |
| <p>Induration (Any): Infant Series Dose 2</p>                                                                                                                                     | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                                    |                               |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[26]</sup></p> <p>occurrences (all)</p> | <p>46 / 178 (25.84%)</p> <p>46</p>                                                                                                                                                                                                                                                      | <p>62 / 175 (35.43%)</p> <p>62</p> | <p>0 / 1 (0.00%)</p> <p>0</p> |
| <p>Induration (Any): Infant Series Dose 3</p>                                                                                                                                     | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                                    |                               |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p>                                                                            |                                                                                                                                                                                                                                                                                         |                                    |                               |

|                                                              |                                                                                                                                                                                                                                                                                  |                   |               |
|--------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|---------------|
| subjects affected / exposed <sup>[27]</sup>                  | 59 / 165 (35.76%)                                                                                                                                                                                                                                                                | 67 / 175 (38.29%) | 0 / 1 (0.00%) |
| occurrences (all)                                            | 59                                                                                                                                                                                                                                                                               | 67                | 0             |
| Induration (mild): Infant Series Dose 1 and Toddler Dose     | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                   |               |
| alternative dictionary used: Local Reactions 0.0             |                                                                                                                                                                                                                                                                                  |                   |               |
| alternative assessment type: Systematic                      |                                                                                                                                                                                                                                                                                  |                   |               |
| subjects affected / exposed <sup>[28]</sup>                  | 33 / 179 (18.44%)                                                                                                                                                                                                                                                                | 41 / 180 (22.78%) | 0 / 1 (0.00%) |
| occurrences (all)                                            | 33                                                                                                                                                                                                                                                                               | 41                | 0             |
| Induration (mild): Infant Series Dose 2                      | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                   |               |
| alternative dictionary used: Local Reactions 0.0             |                                                                                                                                                                                                                                                                                  |                   |               |
| alternative assessment type: Systematic                      |                                                                                                                                                                                                                                                                                  |                   |               |
| subjects affected / exposed <sup>[29]</sup>                  | 37 / 177 (20.90%)                                                                                                                                                                                                                                                                | 54 / 173 (31.21%) | 0 / 1 (0.00%) |
| occurrences (all)                                            | 37                                                                                                                                                                                                                                                                               | 54                | 0             |
| Induration (mild): Infant Series Dose 3                      | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                   |               |
| alternative dictionary used: Local Reactions 0.0             |                                                                                                                                                                                                                                                                                  |                   |               |
| alternative assessment type: Systematic                      |                                                                                                                                                                                                                                                                                  |                   |               |
| subjects affected / exposed <sup>[30]</sup>                  | 51 / 165 (30.91%)                                                                                                                                                                                                                                                                | 56 / 171 (32.75%) | 0 / 1 (0.00%) |
| occurrences (all)                                            | 51                                                                                                                                                                                                                                                                               | 56                | 0             |
| Induration (moderate): Infant Series Dose 1 and Toddler Dose | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                   |               |
| alternative dictionary used: Local Reactions 0.0             |                                                                                                                                                                                                                                                                                  |                   |               |
| alternative assessment type: Systematic                      |                                                                                                                                                                                                                                                                                  |                   |               |
| subjects affected / exposed <sup>[31]</sup>                  | 18 / 179 (10.06%)                                                                                                                                                                                                                                                                | 28 / 182 (15.38%) | 0 / 1 (0.00%) |
| occurrences (all)                                            | 18                                                                                                                                                                                                                                                                               | 28                | 0             |
| Induration (moderate): Infant Series Dose 2                  | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                   |               |
| alternative dictionary used: Local Reactions 0.0             |                                                                                                                                                                                                                                                                                  |                   |               |
| alternative assessment type: Systematic                      |                                                                                                                                                                                                                                                                                  |                   |               |
| subjects affected / exposed <sup>[32]</sup>                  | 22 / 175 (12.57%)                                                                                                                                                                                                                                                                | 24 / 172 (13.95%) | 0 / 1 (0.00%) |
| occurrences (all)                                            | 22                                                                                                                                                                                                                                                                               | 24                | 0             |
| Induration (moderate): Infant Series Dose 3                  | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                   |               |

|                                                                                                                                                                                                                                                 |                   |                   |               |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|-------------------|---------------|
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[33]</sup></p> <p>occurrences (all)</p>                                                               | 23 / 164 (14.02%) | 30 / 169 (17.75%) | 0 / 1 (0.00%) |
| <p>Erythema (Any): Infant Series Dose 1 and Toddler Dose</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[34]</sup></p> <p>occurrences (all)</p>  | 58 / 181 (32.04%) | 73 / 183 (39.89%) | 0 / 1 (0.00%) |
| <p>Erythema (Any): Infant Series Dose 2</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[35]</sup></p> <p>occurrences (all)</p>                   | 68 / 180 (37.78%) | 86 / 178 (48.31%) | 0 / 1 (0.00%) |
| <p>Erythema (Any): Infant Series Dose 3</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[36]</sup></p> <p>occurrences (all)</p>                   | 78 / 169 (46.15%) | 89 / 177 (50.28%) | 0 / 1 (0.00%) |
| <p>Erythema (Mild): Infant Series Dose 1 and Toddler Dose</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[37]</sup></p> <p>occurrences (all)</p> | 56 / 181 (30.94%) | 63 / 180 (35.00%) | 0 / 1 (0.00%) |
| <p>Erythema (Mild): Infant Series Dose 2</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p>                                                                                             |                   |                   |               |

|                                                            |                                                                                                                                                                                                                                                                                  |                   |               |
|------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|---------------|
| subjects affected / exposed <sup>[38]</sup>                | 68 / 180 (37.78%)                                                                                                                                                                                                                                                                | 82 / 177 (46.33%) | 0 / 1 (0.00%) |
| occurrences (all)                                          | 68                                                                                                                                                                                                                                                                               | 82                | 0             |
| Erythema (Mild): Infant Series Dose 3                      | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                   |               |
| alternative dictionary used: Local Reactions 0.0           |                                                                                                                                                                                                                                                                                  |                   |               |
| alternative assessment type: Systematic                    |                                                                                                                                                                                                                                                                                  |                   |               |
| subjects affected / exposed <sup>[39]</sup>                | 78 / 169 (46.15%)                                                                                                                                                                                                                                                                | 82 / 177 (46.33%) | 0 / 1 (0.00%) |
| occurrences (all)                                          | 78                                                                                                                                                                                                                                                                               | 82                | 0             |
| Erythema (Moderate): Infant Series Dose 1 and Toddler Dose | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                   |               |
| alternative dictionary used: Local Reactions 0.0           |                                                                                                                                                                                                                                                                                  |                   |               |
| alternative assessment type: Systematic                    |                                                                                                                                                                                                                                                                                  |                   |               |
| subjects affected / exposed <sup>[40]</sup>                | 3 / 179 (1.68%)                                                                                                                                                                                                                                                                  | 10 / 178 (5.62%)  | 0 / 1 (0.00%) |
| occurrences (all)                                          | 3                                                                                                                                                                                                                                                                                | 10                | 0             |
| Erythema (Moderate): Infant Series Dose 2                  | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                   |               |
| alternative dictionary used: Local Reactions 0.0           |                                                                                                                                                                                                                                                                                  |                   |               |
| alternative assessment type: Systematic                    |                                                                                                                                                                                                                                                                                  |                   |               |
| subjects affected / exposed <sup>[41]</sup>                | 2 / 172 (1.16%)                                                                                                                                                                                                                                                                  | 6 / 171 (3.51%)   | 0 / 1 (0.00%) |
| occurrences (all)                                          | 2                                                                                                                                                                                                                                                                                | 6                 | 0             |
| Erythema (Moderate): Infant Series Dose 3                  | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                   |               |
| alternative dictionary used: Local Reactions 0.0           |                                                                                                                                                                                                                                                                                  |                   |               |
| alternative assessment type: Systematic                    |                                                                                                                                                                                                                                                                                  |                   |               |
| subjects affected / exposed <sup>[42]</sup>                | 5 / 164 (3.05%)                                                                                                                                                                                                                                                                  | 16 / 165 (9.70%)  | 0 / 1 (0.00%) |
| occurrences (all)                                          | 5                                                                                                                                                                                                                                                                                | 16                | 0             |
| Erythema (Severe): Infant Series Dose 1 and Toddler Dose   | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                   |               |
| alternative dictionary used: Local Reactions 0.0           |                                                                                                                                                                                                                                                                                  |                   |               |
| alternative assessment type: Systematic                    |                                                                                                                                                                                                                                                                                  |                   |               |
| subjects affected / exposed <sup>[43]</sup>                | 0 / 179 (0.00%)                                                                                                                                                                                                                                                                  | 0 / 177 (0.00%)   | 0 / 1 (0.00%) |
| occurrences (all)                                          | 0                                                                                                                                                                                                                                                                                | 0                 | 0             |
| Infections and infestations                                |                                                                                                                                                                                                                                                                                  |                   |               |

|                                            |                  |                  |                 |
|--------------------------------------------|------------------|------------------|-----------------|
| Bronchitis                                 |                  |                  |                 |
| alternative assessment type:<br>Systematic |                  |                  |                 |
| subjects affected / exposed                | 23 / 249 (9.24%) | 19 / 250 (7.60%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 24               | 19               | 0               |
| Rhinitis                                   |                  |                  |                 |
| alternative assessment type:<br>Systematic |                  |                  |                 |
| subjects affected / exposed                | 19 / 249 (7.63%) | 21 / 250 (8.40%) | 3 / 249 (1.20%) |
| occurrences (all)                          | 25               | 22               | 3               |
| Pharyngitis                                |                  |                  |                 |
| alternative assessment type:<br>Systematic |                  |                  |                 |
| subjects affected / exposed                | 17 / 249 (6.83%) | 15 / 250 (6.00%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 18               | 17               | 0               |
| Upper respiratory tract infection          |                  |                  |                 |
| alternative assessment type:<br>Systematic |                  |                  |                 |
| subjects affected / exposed                | 17 / 249 (6.83%) | 13 / 250 (5.20%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 19               | 14               | 0               |
| Nasopharyngitis                            |                  |                  |                 |
| alternative assessment type:<br>Systematic |                  |                  |                 |
| subjects affected / exposed                | 13 / 249 (5.22%) | 13 / 250 (5.20%) | 1 / 249 (0.40%) |
| occurrences (all)                          | 16               | 14               | 1               |
| Respiratory tract infection                |                  |                  |                 |
| alternative assessment type:<br>Systematic |                  |                  |                 |
| subjects affected / exposed                | 8 / 249 (3.21%)  | 6 / 250 (2.40%)  | 0 / 249 (0.00%) |
| occurrences (all)                          | 9                | 7                | 0               |
| Urinary tract infection                    |                  |                  |                 |
| alternative assessment type:<br>Systematic |                  |                  |                 |
| subjects affected / exposed                | 7 / 249 (2.81%)  | 1 / 250 (0.40%)  | 0 / 249 (0.00%) |
| occurrences (all)                          | 7                | 1                | 0               |
| Bronchopneumonia                           |                  |                  |                 |
| alternative assessment type:<br>Systematic |                  |                  |                 |
| subjects affected / exposed                | 2 / 249 (0.80%)  | 3 / 250 (1.20%)  | 0 / 249 (0.00%) |
| occurrences (all)                          | 2                | 3                | 0               |
| Pneumonia                                  |                  |                  |                 |
| alternative assessment type:<br>Systematic |                  |                  |                 |

|                                            |                 |                 |                 |
|--------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed                | 3 / 249 (1.20%) | 2 / 250 (0.80%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 3               | 2               | 0               |
| Viral infection                            |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 2 / 249 (0.80%) | 3 / 250 (1.20%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 2               | 3               | 0               |
| Ear infection                              |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 2 / 249 (0.80%) | 2 / 250 (0.80%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 2               | 2               | 0               |
| Gastroenteritis                            |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 3 / 249 (1.20%) | 1 / 250 (0.40%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 3               | 1               | 0               |
| Laryngitis                                 |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 2 / 249 (0.80%) | 1 / 250 (0.40%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 2               | 1               | 0               |
| Otitis media                               |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 2 / 249 (0.80%) | 1 / 250 (0.40%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 2               | 1               | 0               |
| Exanthema subitum                          |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 1 / 249 (0.40%) | 1 / 250 (0.40%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 1               | 1               | 0               |
| Viral upper respiratory tract infection    |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 1 / 249 (0.40%) | 1 / 250 (0.40%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 1               | 1               | 0               |
| Candidiasis                                |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 1 / 249 (0.40%) | 0 / 250 (0.00%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 1               | 0               | 0               |

|                                            |                 |                 |                 |
|--------------------------------------------|-----------------|-----------------|-----------------|
| Conjunctivitis infective                   |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 249 (0.00%) | 1 / 250 (0.40%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 0               | 1               | 0               |
| Gastroenteritis staphylococcal             |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 1 / 249 (0.40%) | 0 / 250 (0.00%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 1               | 0               | 0               |
| Oral candidiasis                           |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 1 / 249 (0.40%) | 0 / 250 (0.00%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 1               | 0               | 0               |
| Perianal abscess                           |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 1 / 249 (0.40%) | 0 / 250 (0.00%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 1               | 0               | 0               |
| Pneumonia primary atypical                 |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 249 (0.00%) | 1 / 250 (0.40%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 0               | 1               | 0               |
| Tinea cruris                               |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 1 / 249 (0.40%) | 0 / 250 (0.00%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 1               | 0               | 0               |
| Tonsillitis                                |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 1 / 249 (0.40%) | 0 / 250 (0.00%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 1               | 0               | 0               |
| Varicella                                  |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 1 / 249 (0.40%) | 0 / 250 (0.00%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 1               | 0               | 0               |
| Viral diarrhoea                            |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |

|                                            |                 |                 |                 |
|--------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed                | 0 / 249 (0.00%) | 1 / 250 (0.40%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 0               | 1               | 0               |
| Viral rash                                 |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 1 / 249 (0.40%) | 0 / 250 (0.00%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 1               | 0               | 0               |
| Hordeolum                                  |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Acute tonsillitis                          |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Influenza                                  |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Metabolism and nutrition disorders         |                 |                 |                 |
| Weight gain poor                           |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) | 0 / 249 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |

| <b>Non-serious adverse events</b>                        | 13vPnC - P80 Post-<br>Infant Series | 13vPnC - P80<br>Toddler Dose | 13vPnC + P80<br>Toddler Dose |
|----------------------------------------------------------|-------------------------------------|------------------------------|------------------------------|
| Total subjects affected by non-serious<br>adverse events |                                     |                              |                              |
| subjects affected / exposed                              | 9 / 250 (3.60%)                     | 111 / 244 (45.49%)           | 91 / 239 (38.08%)            |
| General disorders and administration<br>site conditions  |                                     |                              |                              |
| Pyrexia                                                  |                                     |                              |                              |
| alternative assessment type:<br>Systematic               |                                     |                              |                              |
| subjects affected / exposed                              | 0 / 250 (0.00%)                     | 1 / 244 (0.41%)              | 1 / 239 (0.42%)              |
| occurrences (all)                                        | 0                                   | 1                            | 1                            |
| Irritability                                             |                                     |                              |                              |
| alternative assessment type:<br>Systematic               |                                     |                              |                              |

|                                                                                                       |                                                                                                                                                                                                                                                                                  |                   |                   |
|-------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|-------------------|
| subjects affected / exposed                                                                           | 0 / 250 (0.00%)                                                                                                                                                                                                                                                                  | 0 / 244 (0.00%)   | 0 / 239 (0.00%)   |
| occurrences (all)                                                                                     | 0                                                                                                                                                                                                                                                                                | 0                 | 0                 |
| Injection site induration                                                                             |                                                                                                                                                                                                                                                                                  |                   |                   |
| alternative assessment type:<br>Systematic                                                            |                                                                                                                                                                                                                                                                                  |                   |                   |
| subjects affected / exposed                                                                           | 0 / 250 (0.00%)                                                                                                                                                                                                                                                                  | 0 / 244 (0.00%)   | 0 / 239 (0.00%)   |
| occurrences (all)                                                                                     | 0                                                                                                                                                                                                                                                                                | 0                 | 0                 |
| Injection site nodule                                                                                 |                                                                                                                                                                                                                                                                                  |                   |                   |
| alternative assessment type:<br>Systematic                                                            |                                                                                                                                                                                                                                                                                  |                   |                   |
| subjects affected / exposed                                                                           | 0 / 250 (0.00%)                                                                                                                                                                                                                                                                  | 0 / 244 (0.00%)   | 0 / 239 (0.00%)   |
| occurrences (all)                                                                                     | 0                                                                                                                                                                                                                                                                                | 0                 | 0                 |
| Injection site swelling                                                                               |                                                                                                                                                                                                                                                                                  |                   |                   |
| alternative assessment type:<br>Systematic                                                            |                                                                                                                                                                                                                                                                                  |                   |                   |
| subjects affected / exposed                                                                           | 0 / 250 (0.00%)                                                                                                                                                                                                                                                                  | 0 / 244 (0.00%)   | 0 / 239 (0.00%)   |
| occurrences (all)                                                                                     | 0                                                                                                                                                                                                                                                                                | 0                 | 0                 |
| Fever $\geq 38^{\circ}\text{C}$ but $\leq 39^{\circ}\text{C}$ : Infant Series Dose 1 and Toddler Dose | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                   |                   |
| alternative dictionary used:<br>Systemic Events 0.0                                                   |                                                                                                                                                                                                                                                                                  |                   |                   |
| alternative assessment type:<br>Systematic                                                            |                                                                                                                                                                                                                                                                                  |                   |                   |
| subjects affected / exposed <sup>[1]</sup>                                                            | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 31 / 172 (18.02%) | 39 / 170 (22.94%) |
| occurrences (all)                                                                                     | 0                                                                                                                                                                                                                                                                                | 31                | 39                |
| Fever $\geq 38^{\circ}\text{C}$ but $\leq 39^{\circ}\text{C}$ : Infant Series Dose 2                  | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                   |                   |
| alternative dictionary used:<br>Systemic Events 0.0                                                   |                                                                                                                                                                                                                                                                                  |                   |                   |
| alternative assessment type:<br>Systematic                                                            |                                                                                                                                                                                                                                                                                  |                   |                   |
| subjects affected / exposed <sup>[2]</sup>                                                            | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%)     | 0 / 1 (0.00%)     |
| occurrences (all)                                                                                     | 0                                                                                                                                                                                                                                                                                | 0                 | 0                 |
| Fever $\geq 38^{\circ}\text{C}$ but $\leq 39^{\circ}\text{C}$ : Infant Series Dose 3                  | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                   |                   |
| alternative dictionary used:<br>Systemic Events 0.0                                                   |                                                                                                                                                                                                                                                                                  |                   |                   |
| alternative assessment type:<br>Systematic                                                            |                                                                                                                                                                                                                                                                                  |                   |                   |
| subjects affected / exposed <sup>[3]</sup>                                                            | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%)     | 0 / 1 (0.00%)     |
| occurrences (all)                                                                                     | 0                                                                                                                                                                                                                                                                                | 0                 | 0                 |
| Fever $> 39^{\circ}\text{C}$ but $\leq 40^{\circ}\text{C}$ : Infant Series Dose 1 and Toddler Dose    | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                   |                   |

|                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                         |                                    |                                    |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|------------------------------------|
| <p>alternative dictionary used:<br/>Systemic Events 0.0</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[4]</sup></p> <p>occurrences (all)</p> | <p>0 / 1 (0.00%)</p> <p>0</p>                                                                                                                                                                                                                                                           | <p>3 / 164 (1.83%)</p> <p>3</p>    | <p>4 / 162 (2.47%)</p> <p>4</p>    |
| <p>Fever &gt;39°C but ≤40°C: Infant Series Dose 2</p>                                                                                                                                    | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                                    |                                    |
| <p>alternative dictionary used:<br/>Systemic Events 0.0</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[5]</sup></p> <p>occurrences (all)</p> | <p>0 / 1 (0.00%)</p> <p>0</p>                                                                                                                                                                                                                                                           | <p>0 / 1 (0.00%)</p> <p>0</p>      | <p>0 / 1 (0.00%)</p> <p>0</p>      |
| <p>Fever &gt;39°C but ≤40°C: Infant Series Dose 3</p>                                                                                                                                    | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                                    |                                    |
| <p>alternative dictionary used:<br/>Systemic Events 0.0</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[6]</sup></p> <p>occurrences (all)</p> | <p>0 / 1 (0.00%)</p> <p>0</p>                                                                                                                                                                                                                                                           | <p>0 / 1 (0.00%)</p> <p>0</p>      | <p>0 / 1 (0.00%)</p> <p>0</p>      |
| <p>Decreased appetite: Infant Series Dose 1 and Toddler Dose</p>                                                                                                                         | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                                    |                                    |
| <p>alternative dictionary used:<br/>Systemic Events 0.0</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[7]</sup></p> <p>occurrences (all)</p> | <p>0 / 1 (0.00%)</p> <p>0</p>                                                                                                                                                                                                                                                           | <p>53 / 183 (28.96%)</p> <p>53</p> | <p>45 / 172 (26.16%)</p> <p>45</p> |
| <p>Decreased appetite: Infant Series Dose 2</p>                                                                                                                                          | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                                    |                                    |
| <p>alternative dictionary used:<br/>Systemic Events 0.0</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[8]</sup></p> <p>occurrences (all)</p> | <p>0 / 1 (0.00%)</p> <p>0</p>                                                                                                                                                                                                                                                           | <p>0 / 1 (0.00%)</p> <p>0</p>      | <p>0 / 1 (0.00%)</p> <p>0</p>      |
| <p>Decreased appetite: Infant Series Dose 3</p>                                                                                                                                          | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                                    |                                    |
| <p>alternative dictionary used:<br/>Systemic Events 0.0</p> <p>alternative assessment type:<br/>Systematic</p>                                                                           |                                                                                                                                                                                                                                                                                         |                                    |                                    |

|                                                                                                                                                                       |                                                                                                                                                                                                                                                                                  |                         |                         |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|-------------------------|
| subjects affected / exposed <sup>[9]</sup><br>occurrences (all)                                                                                                       | 0 / 1 (0.00%)<br>0                                                                                                                                                                                                                                                               | 0 / 1 (0.00%)<br>0      | 0 / 1 (0.00%)<br>0      |
| Decreased sleep: Infant Series Dose 1 and Toddler Dose                                                                                                                | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                         |                         |
| alternative dictionary used:<br>Systemic Events 0.0<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed <sup>[10]</sup><br>occurrences (all) | 0 / 1 (0.00%)<br>0                                                                                                                                                                                                                                                               | 46 / 180 (25.56%)<br>46 | 33 / 170 (19.41%)<br>33 |
| Decreased sleep: Infant Series Dose 2                                                                                                                                 | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                         |                         |
| alternative dictionary used:<br>Systemic Events 0.0<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed <sup>[11]</sup><br>occurrences (all) | 0 / 1 (0.00%)<br>0                                                                                                                                                                                                                                                               | 0 / 1 (0.00%)<br>0      | 0 / 1 (0.00%)<br>0      |
| Decreased sleep: Infant Series Dose 3                                                                                                                                 | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                         |                         |
| alternative dictionary used:<br>Systemic Events 0.0<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed <sup>[12]</sup><br>occurrences (all) | 0 / 1 (0.00%)<br>0                                                                                                                                                                                                                                                               | 0 / 1 (0.00%)<br>0      | 0 / 1 (0.00%)<br>0      |
| Increased sleep: Infant Series Dose 1 and Toddler Dose                                                                                                                | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                         |                         |
| alternative dictionary used:<br>Systemic Events 0.0<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed <sup>[13]</sup><br>occurrences (all) | 0 / 1 (0.00%)<br>0                                                                                                                                                                                                                                                               | 56 / 182 (30.77%)<br>56 | 33 / 174 (18.97%)<br>33 |
| Increased sleep: Infant Series Dose 2                                                                                                                                 | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                         |                         |
| alternative dictionary used:<br>Systemic Events 0.0<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed <sup>[14]</sup><br>occurrences (all) | 0 / 1 (0.00%)<br>0                                                                                                                                                                                                                                                               | 0 / 1 (0.00%)<br>0      | 0 / 1 (0.00%)<br>0      |
| Increased sleep: Infant Series Dose 3                                                                                                                                 | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                         |                         |

|                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                         |                                      |                                    |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|------------------------------------|
| <p>alternative dictionary used:<br/>Systemic Events 0.0</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[15]</sup></p> <p>occurrences (all)</p> | <p>0 / 1 (0.00%)</p> <p>0</p>                                                                                                                                                                                                                                                           | <p>0 / 1 (0.00%)</p> <p>0</p>        | <p>0 / 1 (0.00%)</p> <p>0</p>      |
| <p>Irritability: Infant Series Dose 1 and Toddler Dose</p>                                                                                                                                | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                                      |                                    |
| <p>alternative dictionary used:<br/>Systemic Events 0.0</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[16]</sup></p> <p>occurrences (all)</p> | <p>0 / 1 (0.00%)</p> <p>0</p>                                                                                                                                                                                                                                                           | <p>111 / 198 (56.06%)</p> <p>111</p> | <p>91 / 184 (49.46%)</p> <p>91</p> |
| <p>Irritability: Infant Series Dose 2</p>                                                                                                                                                 | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                                      |                                    |
| <p>alternative dictionary used:<br/>Systemic Events 0.0</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[17]</sup></p> <p>occurrences (all)</p> | <p>0 / 1 (0.00%)</p> <p>0</p>                                                                                                                                                                                                                                                           | <p>0 / 1 (0.00%)</p> <p>0</p>        | <p>0 / 1 (0.00%)</p> <p>0</p>      |
| <p>Irritability: Infant Series Dose 3</p>                                                                                                                                                 | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                                      |                                    |
| <p>alternative dictionary used:<br/>Systemic Events 0.0</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[18]</sup></p> <p>occurrences (all)</p> | <p>0 / 1 (0.00%)</p> <p>0</p>                                                                                                                                                                                                                                                           | <p>0 / 1 (0.00%)</p> <p>0</p>        | <p>0 / 1 (0.00%)</p> <p>0</p>      |
| <p>Immune system disorders</p> <p>Food allergy</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>                         | <p>0 / 250 (0.00%)</p> <p>0</p>                                                                                                                                                                                                                                                         | <p>1 / 244 (0.41%)</p> <p>1</p>      | <p>0 / 239 (0.00%)</p> <p>0</p>    |
| <p>Respiratory, thoracic and mediastinal disorders</p> <p>Cough</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>        | <p>0 / 250 (0.00%)</p> <p>0</p>                                                                                                                                                                                                                                                         | <p>0 / 244 (0.00%)</p> <p>0</p>      | <p>0 / 239 (0.00%)</p> <p>0</p>    |
| <p>Interstitial lung disease</p> <p>alternative assessment type:<br/>Systematic</p>                                                                                                       |                                                                                                                                                                                                                                                                                         |                                      |                                    |

|                                                                                                         |                      |                      |                      |
|---------------------------------------------------------------------------------------------------------|----------------------|----------------------|----------------------|
| subjects affected / exposed<br>occurrences (all)                                                        | 0 / 250 (0.00%)<br>0 | 0 / 244 (0.00%)<br>0 | 0 / 239 (0.00%)<br>0 |
| Pharyngolaryngeal pain<br>alternative assessment type:<br>Systematic                                    |                      |                      |                      |
| subjects affected / exposed<br>occurrences (all)                                                        | 0 / 250 (0.00%)<br>0 | 0 / 244 (0.00%)<br>0 | 0 / 239 (0.00%)<br>0 |
| Rhinitis allergic<br>alternative assessment type:<br>Systematic                                         |                      |                      |                      |
| subjects affected / exposed<br>occurrences (all)                                                        | 1 / 250 (0.40%)<br>1 | 0 / 244 (0.00%)<br>0 | 0 / 239 (0.00%)<br>0 |
| Psychiatric disorders<br>Decreased activity<br>alternative assessment type:<br>Systematic               |                      |                      |                      |
| subjects affected / exposed<br>occurrences (all)                                                        | 0 / 250 (0.00%)<br>0 | 0 / 244 (0.00%)<br>0 | 0 / 239 (0.00%)<br>0 |
| Insomnia<br>alternative assessment type:<br>Systematic                                                  |                      |                      |                      |
| subjects affected / exposed<br>occurrences (all)                                                        | 0 / 250 (0.00%)<br>0 | 0 / 244 (0.00%)<br>0 | 0 / 239 (0.00%)<br>0 |
| Investigations<br>Cardiac murmur functional<br>alternative assessment type:<br>Systematic               |                      |                      |                      |
| subjects affected / exposed<br>occurrences (all)                                                        | 0 / 250 (0.00%)<br>0 | 0 / 244 (0.00%)<br>0 | 0 / 239 (0.00%)<br>0 |
| Cardiac murmur<br>alternative assessment type:<br>Systematic                                            |                      |                      |                      |
| subjects affected / exposed<br>occurrences (all)                                                        | 1 / 250 (0.40%)<br>1 | 0 / 244 (0.00%)<br>0 | 0 / 239 (0.00%)<br>0 |
| Congenital, familial and genetic disorders<br>Craniotabes<br>alternative assessment type:<br>Systematic |                      |                      |                      |
| subjects affected / exposed<br>occurrences (all)                                                        | 0 / 250 (0.00%)<br>0 | 0 / 244 (0.00%)<br>0 | 0 / 239 (0.00%)<br>0 |
| Dacryostenosis congenital<br>alternative assessment type:<br>Systematic                                 |                      |                      |                      |

|                                            |                 |                 |                 |
|--------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Brachycephaly                              |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 1 / 250 (0.40%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 1               | 0               | 0               |
| Cryptorchism                               |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 1 / 244 (0.41%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 1               | 0               |
| Ventricular septal defect                  |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 1 / 250 (0.40%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 1               | 0               | 0               |
| Cardiac disorders                          |                 |                 |                 |
| Aortic valve incompetence                  |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 1 / 250 (0.40%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 1               | 0               | 0               |
| Tricuspid valve incompetence               |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 1 / 250 (0.40%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 1               | 0               | 0               |
| Nervous system disorders                   |                 |                 |                 |
| Hypertonia                                 |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Hypotonia                                  |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Blood and lymphatic system disorders       |                 |                 |                 |
| Anaemia                                    |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                 |                                                                                                                                 |                                                                                                                                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Iron deficiency anaemia</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <p>0 / 250 (0.00%)</p> <p>0</p> <p>0 / 250 (0.00%)</p> <p>0</p>                                                                                                 | <p>0 / 244 (0.00%)</p> <p>0</p> <p>0 / 244 (0.00%)</p> <p>0</p>                                                                 | <p>0 / 239 (0.00%)</p> <p>0</p> <p>0 / 239 (0.00%)</p> <p>0</p>                                                                 |
| <p>Eye disorders</p> <p>Conjunctivitis</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <p>0 / 250 (0.00%)</p> <p>0</p>                                                                                                                                 | <p>3 / 244 (1.23%)</p> <p>3</p>                                                                                                 | <p>0 / 239 (0.00%)</p> <p>0</p>                                                                                                 |
| <p>Gastrointestinal disorders</p> <p>Diarrhoea</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Vomiting</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Abdominal pain</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Haematochezia</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Abdominal distension</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Aphthous stomatitis</p> <p>alternative assessment type: Systematic</p> | <p>0 / 250 (0.00%)</p> <p>0</p> <p>0 / 250 (0.00%)</p> <p>0</p> <p>0 / 250 (0.00%)</p> <p>0</p> <p>0 / 250 (0.00%)</p> <p>0</p> <p>0 / 250 (0.00%)</p> <p>0</p> | <p>5 / 244 (2.05%)</p> <p>5</p> <p>0 / 244 (0.00%)</p> <p>0</p> <p>0 / 244 (0.00%)</p> <p>0</p> <p>0 / 244 (0.00%)</p> <p>0</p> | <p>4 / 239 (1.67%)</p> <p>4</p> <p>1 / 239 (0.42%)</p> <p>2</p> <p>0 / 239 (0.00%)</p> <p>0</p> <p>0 / 239 (0.00%)</p> <p>0</p> |

|                                            |                 |                 |                 |
|--------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Constipation                               |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Dyspepsia                                  |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 1 / 239 (0.42%) |
| occurrences (all)                          | 0               | 0               | 1               |
| Infantile colic                            |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Umbilical hernia                           |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Gastrooesophageal reflux disease           |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Stomatitis                                 |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 1 / 239 (0.42%) |
| occurrences (all)                          | 0               | 0               | 1               |
| Skin and subcutaneous tissue disorders     |                 |                 |                 |
| Dermatitis atopic                          |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 1 / 250 (0.40%) | 1 / 244 (0.41%) | 2 / 239 (0.84%) |
| occurrences (all)                          | 1               | 1               | 2               |
| Dermatitis allergic                        |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |

|                                            |                 |                 |                 |
|--------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed                | 2 / 250 (0.80%) | 1 / 244 (0.41%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 2               | 1               | 0               |
| Rash                                       |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Dermatitis                                 |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Dermatitis diaper                          |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Heat rash                                  |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Dermatitis contact                         |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Hyperhidrosis                              |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Seborrhoeic dermatitis                     |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Skin inflammation                          |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |

|                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                  |                         |                         |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|-------------------------|
| Urticaria<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                                                                                                                               | 0 / 250 (0.00%)<br>0                                                                                                                                                                                                                                                             | 0 / 244 (0.00%)<br>0    | 0 / 239 (0.00%)<br>0    |
| Tenderness (Any): Infant Series Dose 1 and Toddler Dose<br><br>alternative dictionary used: Local Reactions 0.0<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed <sup>[19]</sup><br>occurrences (all)         | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                         |                         |
|                                                                                                                                                                                                                                           | 0 / 1 (0.00%)<br>0                                                                                                                                                                                                                                                               | 81 / 188 (43.09%)<br>81 | 75 / 178 (42.13%)<br>75 |
| Tenderness (Any): Infant Series Dose 2<br><br>alternative dictionary used: Local Reactions 0.0<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed <sup>[20]</sup><br>occurrences (all)                          | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                         |                         |
|                                                                                                                                                                                                                                           | 0 / 1 (0.00%)<br>0                                                                                                                                                                                                                                                               | 0 / 1 (0.00%)<br>0      | 0 / 1 (0.00%)<br>0      |
| Tenderness (Any): Infant Series Dose 3<br><br>alternative dictionary used: Local Reactions 0.0<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed <sup>[21]</sup><br>occurrences (all)                          | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                         |                         |
|                                                                                                                                                                                                                                           | 0 / 1 (0.00%)<br>0                                                                                                                                                                                                                                                               | 0 / 1 (0.00%)<br>0      | 0 / 1 (0.00%)<br>0      |
| Tenderness (significant): Infant Series Dose 1 and Toddler Dose<br><br>alternative dictionary used: Local Reactions 0.0<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed <sup>[22]</sup><br>occurrences (all) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                         |                         |
|                                                                                                                                                                                                                                           | 0 / 1 (0.00%)<br>0                                                                                                                                                                                                                                                               | 2 / 165 (1.21%)<br>2    | 4 / 160 (2.50%)<br>4    |
| Tenderness (significant): Infant Series Dose 2<br><br>alternative dictionary used: Local Reactions 0.0<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed <sup>[23]</sup><br>occurrences (all)                  | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                         |                         |
|                                                                                                                                                                                                                                           | 0 / 1 (0.00%)<br>0                                                                                                                                                                                                                                                               | 0 / 1 (0.00%)<br>0      | 0 / 1 (0.00%)<br>0      |

|                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                         |                   |                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|-------------------|
| <p>Tenderness (significant): Infant Series Dose 3</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[24]</sup></p> <p>occurrences (all)</p>           | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                   |                   |
|                                                                                                                                                                                                                                                   | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                           | 0 / 1 (0.00%)     | 0 / 1 (0.00%)     |
|                                                                                                                                                                                                                                                   | 0                                                                                                                                                                                                                                                                                       | 0                 | 0                 |
| <p>Induration (Any): Infant Series Dose 1 and Toddler Dose</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[25]</sup></p> <p>occurrences (all)</p>  | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                   |                   |
|                                                                                                                                                                                                                                                   | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                           | 63 / 181 (34.81%) | 52 / 174 (29.89%) |
|                                                                                                                                                                                                                                                   | 0                                                                                                                                                                                                                                                                                       | 63                | 52                |
| <p>Induration (Any): Infant Series Dose 2</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[26]</sup></p> <p>occurrences (all)</p>                   | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                   |                   |
|                                                                                                                                                                                                                                                   | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                           | 0 / 1 (0.00%)     | 0 / 1 (0.00%)     |
|                                                                                                                                                                                                                                                   | 0                                                                                                                                                                                                                                                                                       | 0                 | 0                 |
| <p>Induration (Any): Infant Series Dose 3</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[27]</sup></p> <p>occurrences (all)</p>                   | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                   |                   |
|                                                                                                                                                                                                                                                   | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                           | 0 / 1 (0.00%)     | 0 / 1 (0.00%)     |
|                                                                                                                                                                                                                                                   | 0                                                                                                                                                                                                                                                                                       | 0                 | 0                 |
| <p>Induration (mild): Infant Series Dose 1 and Toddler Dose</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[28]</sup></p> <p>occurrences (all)</p> | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                   |                   |
|                                                                                                                                                                                                                                                   | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                           | 53 / 178 (29.78%) | 45 / 169 (26.63%) |
|                                                                                                                                                                                                                                                   | 0                                                                                                                                                                                                                                                                                       | 53                | 45                |
| <p>Induration (mild): Infant Series Dose 2</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p>                                                                                             | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                   |                   |
|                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                         |                   |                   |

|                                                              |                                                                                                                                                                                                                                                                                  |                    |                   |
|--------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|-------------------|
| subjects affected / exposed <sup>[29]</sup>                  | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%)      | 0 / 1 (0.00%)     |
| occurrences (all)                                            | 0                                                                                                                                                                                                                                                                                | 0                  | 0                 |
| Induration (mild): Infant Series Dose 3                      | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                    |                   |
| alternative dictionary used: Local Reactions 0.0             |                                                                                                                                                                                                                                                                                  |                    |                   |
| alternative assessment type: Systematic                      |                                                                                                                                                                                                                                                                                  |                    |                   |
| subjects affected / exposed <sup>[30]</sup>                  | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%)      | 0 / 1 (0.00%)     |
| occurrences (all)                                            | 0                                                                                                                                                                                                                                                                                | 0                  | 0                 |
| Induration (moderate): Infant Series Dose 1 and Toddler Dose | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                    |                   |
| alternative dictionary used: Local Reactions 0.0             |                                                                                                                                                                                                                                                                                  |                    |                   |
| alternative assessment type: Systematic                      |                                                                                                                                                                                                                                                                                  |                    |                   |
| subjects affected / exposed <sup>[31]</sup>                  | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 34 / 171 (19.88%)  | 20 / 164 (12.20%) |
| occurrences (all)                                            | 0                                                                                                                                                                                                                                                                                | 34                 | 20                |
| Induration (moderate): Infant Series Dose 2                  | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                    |                   |
| alternative dictionary used: Local Reactions 0.0             |                                                                                                                                                                                                                                                                                  |                    |                   |
| alternative assessment type: Systematic                      |                                                                                                                                                                                                                                                                                  |                    |                   |
| subjects affected / exposed <sup>[32]</sup>                  | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%)      | 0 / 1 (0.00%)     |
| occurrences (all)                                            | 0                                                                                                                                                                                                                                                                                | 0                  | 0                 |
| Induration (moderate): Infant Series Dose 3                  | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                    |                   |
| alternative dictionary used: Local Reactions 0.0             |                                                                                                                                                                                                                                                                                  |                    |                   |
| alternative assessment type: Systematic                      |                                                                                                                                                                                                                                                                                  |                    |                   |
| subjects affected / exposed <sup>[33]</sup>                  | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%)      | 0 / 1 (0.00%)     |
| occurrences (all)                                            | 0                                                                                                                                                                                                                                                                                | 0                  | 0                 |
| Erythema (Any): Infant Series Dose 1 and Toddler Dose        | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                    |                   |
| alternative dictionary used: Local Reactions 0.0             |                                                                                                                                                                                                                                                                                  |                    |                   |
| alternative assessment type: Systematic                      |                                                                                                                                                                                                                                                                                  |                    |                   |
| subjects affected / exposed <sup>[34]</sup>                  | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 104 / 200 (52.00%) | 75 / 178 (42.13%) |
| occurrences (all)                                            | 0                                                                                                                                                                                                                                                                                | 104                | 75                |
| Erythema (Any): Infant Series Dose 2                         | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                    |                   |

|                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                         |                   |                   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|-------------------|
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[35]</sup></p> <p>occurrences (all)</p>                                                               | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                           | 0 / 1 (0.00%)     | 0 / 1 (0.00%)     |
| <p>Erythema (Any): Infant Series Dose 3</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[36]</sup></p> <p>occurrences (all)</p>                   | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                   |                   |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[36]</sup></p> <p>occurrences (all)</p>                                                               | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                           | 0 / 1 (0.00%)     | 0 / 1 (0.00%)     |
| <p>Erythema (Mild): Infant Series Dose 1 and Toddler Dose</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[37]</sup></p> <p>occurrences (all)</p> | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                   |                   |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[37]</sup></p> <p>occurrences (all)</p>                                                               | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                           | 90 / 194 (46.39%) | 63 / 176 (35.80%) |
| <p>Erythema (Mild): Infant Series Dose 2</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[38]</sup></p> <p>occurrences (all)</p>                  | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                   |                   |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[38]</sup></p> <p>occurrences (all)</p>                                                               | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                           | 0 / 1 (0.00%)     | 0 / 1 (0.00%)     |
| <p>Erythema (Mild): Infant Series Dose 3</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[39]</sup></p> <p>occurrences (all)</p>                  | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                   |                   |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[39]</sup></p> <p>occurrences (all)</p>                                                               | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                           | 0 / 1 (0.00%)     | 0 / 1 (0.00%)     |
| <p>Erythema (Moderate): Infant Series Dose 1 and Toddler Dose</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p>                                                                        | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                   |                   |

|                                                          |                                                                                                                                                                                                                                                                                  |                   |                   |
|----------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|-------------------|
| subjects affected / exposed <sup>[40]</sup>              | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 34 / 173 (19.65%) | 21 / 164 (12.80%) |
| occurrences (all)                                        | 0                                                                                                                                                                                                                                                                                | 34                | 21                |
| Erythema (Moderate): Infant Series Dose 2                | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                   |                   |
| alternative dictionary used: Local Reactions 0.0         |                                                                                                                                                                                                                                                                                  |                   |                   |
| alternative assessment type: Systematic                  |                                                                                                                                                                                                                                                                                  |                   |                   |
| subjects affected / exposed <sup>[41]</sup>              | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%)     | 0 / 1 (0.00%)     |
| occurrences (all)                                        | 0                                                                                                                                                                                                                                                                                | 0                 | 0                 |
| Erythema (Moderate): Infant Series Dose 3                | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                   |                   |
| alternative dictionary used: Local Reactions 0.0         |                                                                                                                                                                                                                                                                                  |                   |                   |
| alternative assessment type: Systematic                  |                                                                                                                                                                                                                                                                                  |                   |                   |
| subjects affected / exposed <sup>[42]</sup>              | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%)     | 0 / 1 (0.00%)     |
| occurrences (all)                                        | 0                                                                                                                                                                                                                                                                                | 0                 | 0                 |
| Erythema (Severe): Infant Series Dose 1 and Toddler Dose | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                   |                   |
| alternative dictionary used: Local Reactions 0.0         |                                                                                                                                                                                                                                                                                  |                   |                   |
| alternative assessment type: Systematic                  |                                                                                                                                                                                                                                                                                  |                   |                   |
| subjects affected / exposed <sup>[43]</sup>              | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 1 / 164 (0.61%)   | 0 / 159 (0.00%)   |
| occurrences (all)                                        | 0                                                                                                                                                                                                                                                                                | 1                 | 0                 |
| Infections and infestations                              |                                                                                                                                                                                                                                                                                  |                   |                   |
| Bronchitis                                               |                                                                                                                                                                                                                                                                                  |                   |                   |
| alternative assessment type: Systematic                  |                                                                                                                                                                                                                                                                                  |                   |                   |
| subjects affected / exposed                              | 0 / 250 (0.00%)                                                                                                                                                                                                                                                                  | 6 / 244 (2.46%)   | 3 / 239 (1.26%)   |
| occurrences (all)                                        | 0                                                                                                                                                                                                                                                                                | 6                 | 3                 |
| Rhinitis                                                 |                                                                                                                                                                                                                                                                                  |                   |                   |
| alternative assessment type: Systematic                  |                                                                                                                                                                                                                                                                                  |                   |                   |
| subjects affected / exposed                              | 1 / 250 (0.40%)                                                                                                                                                                                                                                                                  | 10 / 244 (4.10%)  | 8 / 239 (3.35%)   |
| occurrences (all)                                        | 1                                                                                                                                                                                                                                                                                | 11                | 8                 |
| Pharyngitis                                              |                                                                                                                                                                                                                                                                                  |                   |                   |
| alternative assessment type: Systematic                  |                                                                                                                                                                                                                                                                                  |                   |                   |
| subjects affected / exposed                              | 0 / 250 (0.00%)                                                                                                                                                                                                                                                                  | 19 / 244 (7.79%)  | 10 / 239 (4.18%)  |
| occurrences (all)                                        | 0                                                                                                                                                                                                                                                                                | 19                | 10                |
| Upper respiratory tract infection                        |                                                                                                                                                                                                                                                                                  |                   |                   |

|                                            |                 |                  |                 |
|--------------------------------------------|-----------------|------------------|-----------------|
| alternative assessment type:<br>Systematic |                 |                  |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 17 / 244 (6.97%) | 9 / 239 (3.77%) |
| occurrences (all)                          | 0               | 19               | 9               |
| Nasopharyngitis                            |                 |                  |                 |
| alternative assessment type:<br>Systematic |                 |                  |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 10 / 244 (4.10%) | 4 / 239 (1.67%) |
| occurrences (all)                          | 0               | 10               | 4               |
| Respiratory tract infection                |                 |                  |                 |
| alternative assessment type:<br>Systematic |                 |                  |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 1 / 244 (0.41%)  | 2 / 239 (0.84%) |
| occurrences (all)                          | 0               | 1                | 2               |
| Urinary tract infection                    |                 |                  |                 |
| alternative assessment type:<br>Systematic |                 |                  |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%)  | 1 / 239 (0.42%) |
| occurrences (all)                          | 0               | 0                | 1               |
| Bronchopneumonia                           |                 |                  |                 |
| alternative assessment type:<br>Systematic |                 |                  |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%)  | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0                | 0               |
| Pneumonia                                  |                 |                  |                 |
| alternative assessment type:<br>Systematic |                 |                  |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%)  | 2 / 239 (0.84%) |
| occurrences (all)                          | 0               | 0                | 2               |
| Viral infection                            |                 |                  |                 |
| alternative assessment type:<br>Systematic |                 |                  |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 1 / 244 (0.41%)  | 1 / 239 (0.42%) |
| occurrences (all)                          | 0               | 1                | 1               |
| Ear infection                              |                 |                  |                 |
| alternative assessment type:<br>Systematic |                 |                  |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%)  | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0                | 0               |
| Gastroenteritis                            |                 |                  |                 |
| alternative assessment type:<br>Systematic |                 |                  |                 |

|                                            |                 |                 |                 |
|--------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed                | 0 / 250 (0.00%) | 1 / 244 (0.41%) | 3 / 239 (1.26%) |
| occurrences (all)                          | 0               | 1               | 3               |
| Laryngitis                                 |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 4 / 244 (1.64%) | 1 / 239 (0.42%) |
| occurrences (all)                          | 0               | 4               | 1               |
| Otitis media                               |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 2 / 244 (0.82%) | 1 / 239 (0.42%) |
| occurrences (all)                          | 0               | 2               | 1               |
| Exanthema subitum                          |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 5 / 244 (2.05%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 5               | 0               |
| Viral upper respiratory tract infection    |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Candidiasis                                |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Conjunctivitis infective                   |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Gastroenteritis staphylococcal             |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Oral candidiasis                           |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |

|                                            |                 |                 |                 |
|--------------------------------------------|-----------------|-----------------|-----------------|
| Perianal abscess                           |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Pneumonia primary atypical                 |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Tinea cruris                               |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Tonsillitis                                |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 1 / 244 (0.41%) | 1 / 239 (0.42%) |
| occurrences (all)                          | 0               | 1               | 1               |
| Varicella                                  |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 1 / 244 (0.41%) | 1 / 239 (0.42%) |
| occurrences (all)                          | 0               | 1               | 1               |
| Viral diarrhoea                            |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Viral rash                                 |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |
| Hordeolum                                  |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 1 / 250 (0.40%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 1               | 0               | 0               |
| Acute tonsillitis                          |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |

|                                            |                 |                 |                 |
|--------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed                | 0 / 250 (0.00%) | 2 / 244 (0.82%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 2               | 0               |
| Influenza                                  |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 0 / 250 (0.00%) | 0 / 244 (0.00%) | 1 / 239 (0.42%) |
| occurrences (all)                          | 0               | 0               | 1               |
| Metabolism and nutrition disorders         |                 |                 |                 |
| Weight gain poor                           |                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |                 |
| subjects affected / exposed                | 1 / 250 (0.40%) | 0 / 244 (0.00%) | 0 / 239 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0               |

| <b>Non-serious adverse events</b>                     | 13vPnC + P80 6-Month Follow-up | 13vPnC - P80 6-Month Follow-up |  |
|-------------------------------------------------------|--------------------------------|--------------------------------|--|
| Total subjects affected by non-serious adverse events |                                |                                |  |
| subjects affected / exposed                           | 0 / 249 (0.00%)                | 1 / 250 (0.40%)                |  |
| General disorders and administration site conditions  |                                |                                |  |
| Pyrexia                                               |                                |                                |  |
| alternative assessment type:<br>Systematic            |                                |                                |  |
| subjects affected / exposed                           | 0 / 249 (0.00%)                | 0 / 250 (0.00%)                |  |
| occurrences (all)                                     | 0                              | 0                              |  |
| Irritability                                          |                                |                                |  |
| alternative assessment type:<br>Systematic            |                                |                                |  |
| subjects affected / exposed                           | 0 / 249 (0.00%)                | 0 / 250 (0.00%)                |  |
| occurrences (all)                                     | 0                              | 0                              |  |
| Injection site induration                             |                                |                                |  |
| alternative assessment type:<br>Systematic            |                                |                                |  |
| subjects affected / exposed                           | 0 / 249 (0.00%)                | 0 / 250 (0.00%)                |  |
| occurrences (all)                                     | 0                              | 0                              |  |
| Injection site nodule                                 |                                |                                |  |
| alternative assessment type:<br>Systematic            |                                |                                |  |
| subjects affected / exposed                           | 0 / 249 (0.00%)                | 0 / 250 (0.00%)                |  |
| occurrences (all)                                     | 0                              | 0                              |  |
| Injection site swelling                               |                                |                                |  |
| alternative assessment type:<br>Systematic            |                                |                                |  |

|                                                                                                       |                                                                                                                                                                                                                                                                                  |                 |  |
|-------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--|
| subjects affected / exposed                                                                           | 0 / 249 (0.00%)                                                                                                                                                                                                                                                                  | 0 / 250 (0.00%) |  |
| occurrences (all)                                                                                     | 0                                                                                                                                                                                                                                                                                | 0               |  |
| Fever $\geq 38^{\circ}\text{C}$ but $\leq 39^{\circ}\text{C}$ : Infant Series Dose 1 and Toddler Dose | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                 |  |
| alternative dictionary used:<br>Systemic Events 0.0                                                   |                                                                                                                                                                                                                                                                                  |                 |  |
| alternative assessment type:<br>Systematic                                                            |                                                                                                                                                                                                                                                                                  |                 |  |
| subjects affected / exposed <sup>[1]</sup>                                                            | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%)   |  |
| occurrences (all)                                                                                     | 0                                                                                                                                                                                                                                                                                | 0               |  |
| Fever $\geq 38^{\circ}\text{C}$ but $\leq 39^{\circ}\text{C}$ : Infant Series Dose 2                  | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                 |  |
| alternative dictionary used:<br>Systemic Events 0.0                                                   |                                                                                                                                                                                                                                                                                  |                 |  |
| alternative assessment type:<br>Systematic                                                            |                                                                                                                                                                                                                                                                                  |                 |  |
| subjects affected / exposed <sup>[2]</sup>                                                            | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%)   |  |
| occurrences (all)                                                                                     | 0                                                                                                                                                                                                                                                                                | 0               |  |
| Fever $\geq 38^{\circ}\text{C}$ but $\leq 39^{\circ}\text{C}$ : Infant Series Dose 3                  | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                 |  |
| alternative dictionary used:<br>Systemic Events 0.0                                                   |                                                                                                                                                                                                                                                                                  |                 |  |
| alternative assessment type:<br>Systematic                                                            |                                                                                                                                                                                                                                                                                  |                 |  |
| subjects affected / exposed <sup>[3]</sup>                                                            | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%)   |  |
| occurrences (all)                                                                                     | 0                                                                                                                                                                                                                                                                                | 0               |  |
| Fever $> 39^{\circ}\text{C}$ but $\leq 40^{\circ}\text{C}$ : Infant Series Dose 1 and Toddler Dose    | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                 |  |
| alternative dictionary used:<br>Systemic Events 0.0                                                   |                                                                                                                                                                                                                                                                                  |                 |  |
| alternative assessment type:<br>Systematic                                                            |                                                                                                                                                                                                                                                                                  |                 |  |
| subjects affected / exposed <sup>[4]</sup>                                                            | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%)   |  |
| occurrences (all)                                                                                     | 0                                                                                                                                                                                                                                                                                | 0               |  |
| Fever $> 39^{\circ}\text{C}$ but $\leq 40^{\circ}\text{C}$ : Infant Series Dose 2                     | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                 |  |
| alternative dictionary used:<br>Systemic Events 0.0                                                   |                                                                                                                                                                                                                                                                                  |                 |  |
| alternative assessment type:<br>Systematic                                                            |                                                                                                                                                                                                                                                                                  |                 |  |
| subjects affected / exposed <sup>[5]</sup>                                                            | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%)   |  |
| occurrences (all)                                                                                     | 0                                                                                                                                                                                                                                                                                | 0               |  |
| Fever $> 39^{\circ}\text{C}$ but $\leq 40^{\circ}\text{C}$ : Infant Series Dose 3                     | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                 |  |

|                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                  |               |  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|--|
| <p>alternative dictionary used:<br/>Systemic Events 0.0</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[6]</sup></p> <p>occurrences (all)</p>  | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%) |  |
| Decreased appetite: Infant Series Dose 1 and Toddler Dose                                                                                                                                 | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |               |  |
| <p>alternative dictionary used:<br/>Systemic Events 0.0</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[7]</sup></p> <p>occurrences (all)</p>  | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%) |  |
| Decreased appetite: Infant Series Dose 2                                                                                                                                                  | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |               |  |
| <p>alternative dictionary used:<br/>Systemic Events 0.0</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[8]</sup></p> <p>occurrences (all)</p>  | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%) |  |
| Decreased appetite: Infant Series Dose 3                                                                                                                                                  | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |               |  |
| <p>alternative dictionary used:<br/>Systemic Events 0.0</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[9]</sup></p> <p>occurrences (all)</p>  | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%) |  |
| Decreased sleep: Infant Series Dose 1 and Toddler Dose                                                                                                                                    | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |               |  |
| <p>alternative dictionary used:<br/>Systemic Events 0.0</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[10]</sup></p> <p>occurrences (all)</p> | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%) |  |
| Decreased sleep: Infant Series Dose 2                                                                                                                                                     | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |               |  |
| <p>alternative dictionary used:<br/>Systemic Events 0.0</p> <p>alternative assessment type:<br/>Systematic</p>                                                                            |                                                                                                                                                                                                                                                                                  |               |  |

|                                                        |                                                                                                                                                                                                                                                                                  |               |  |
|--------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|--|
| subjects affected / exposed <sup>[11]</sup>            | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%) |  |
| occurrences (all)                                      | 0                                                                                                                                                                                                                                                                                | 0             |  |
| Decreased sleep: Infant Series Dose 3                  | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |               |  |
| alternative dictionary used:<br>Systemic Events 0.0    |                                                                                                                                                                                                                                                                                  |               |  |
| alternative assessment type:<br>Systematic             |                                                                                                                                                                                                                                                                                  |               |  |
| subjects affected / exposed <sup>[12]</sup>            | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%) |  |
| occurrences (all)                                      | 0                                                                                                                                                                                                                                                                                | 0             |  |
| Increased sleep: Infant Series Dose 1 and Toddler Dose | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |               |  |
| alternative dictionary used:<br>Systemic Events 0.0    |                                                                                                                                                                                                                                                                                  |               |  |
| alternative assessment type:<br>Systematic             |                                                                                                                                                                                                                                                                                  |               |  |
| subjects affected / exposed <sup>[13]</sup>            | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%) |  |
| occurrences (all)                                      | 0                                                                                                                                                                                                                                                                                | 0             |  |
| Increased sleep: Infant Series Dose 2                  | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |               |  |
| alternative dictionary used:<br>Systemic Events 0.0    |                                                                                                                                                                                                                                                                                  |               |  |
| alternative assessment type:<br>Systematic             |                                                                                                                                                                                                                                                                                  |               |  |
| subjects affected / exposed <sup>[14]</sup>            | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%) |  |
| occurrences (all)                                      | 0                                                                                                                                                                                                                                                                                | 0             |  |
| Increased sleep: Infant Series Dose 3                  | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |               |  |
| alternative dictionary used:<br>Systemic Events 0.0    |                                                                                                                                                                                                                                                                                  |               |  |
| alternative assessment type:<br>Systematic             |                                                                                                                                                                                                                                                                                  |               |  |
| subjects affected / exposed <sup>[15]</sup>            | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%) |  |
| occurrences (all)                                      | 0                                                                                                                                                                                                                                                                                | 0             |  |
| Irritability: Infant Series Dose 1 and Toddler Dose    | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |               |  |
| alternative dictionary used:<br>Systemic Events 0.0    |                                                                                                                                                                                                                                                                                  |               |  |
| alternative assessment type:<br>Systematic             |                                                                                                                                                                                                                                                                                  |               |  |
| subjects affected / exposed <sup>[16]</sup>            | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%) |  |
| occurrences (all)                                      | 0                                                                                                                                                                                                                                                                                | 0             |  |
| Irritability: Infant Series Dose 2                     | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |               |  |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                   |                                                                                                          |  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|--|
| alternative dictionary used:<br>Systemic Events 0.0<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed <sup>[17]</sup><br>occurrences (all)                                                                                                                                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%)<br>0                                                                                                                                                                                                                                                                | 0 / 1 (0.00%)<br>0                                                                                       |  |
| Irritability: Infant Series Dose 3<br><br>alternative dictionary used:<br>Systemic Events 0.0<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed <sup>[18]</sup><br>occurrences (all)                                                                                                                                                                                                                                                                                                                                          | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                                                                                                          |  |
| Immune system disorders<br>Food allergy<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                                                                                                                                                | 0 / 249 (0.00%)<br>0                                                                                                                                                                                                                                                              | 0 / 250 (0.00%)<br>0                                                                                     |  |
| Respiratory, thoracic and mediastinal disorders<br>Cough<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Interstitial lung disease<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Pharyngolaryngeal pain<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Rhinitis allergic<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all) | 0 / 249 (0.00%)<br>0<br><br>0 / 249 (0.00%)<br>0<br><br>0 / 249 (0.00%)<br>0<br><br>0 / 249 (0.00%)<br>0                                                                                                                                                                          | 0 / 250 (0.00%)<br>0<br><br>0 / 250 (0.00%)<br>0<br><br>0 / 250 (0.00%)<br>0<br><br>0 / 250 (0.00%)<br>0 |  |
| Psychiatric disorders                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                   |                                                                                                          |  |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                      |                                                                                                          |  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|--|
| Decreased activity<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 0 / 249 (0.00%)<br>0                                                                                                                 | 0 / 250 (0.00%)<br>0                                                                                     |  |
| Insomnia<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 0 / 249 (0.00%)<br>0                                                                                                                 | 0 / 250 (0.00%)<br>0                                                                                     |  |
| Investigations<br>Cardiac murmur functional<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Cardiac murmur<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                                        | 0 / 249 (0.00%)<br>0<br><br>0 / 249 (0.00%)<br>0                                                                                     | 0 / 250 (0.00%)<br>0<br><br>0 / 250 (0.00%)<br>0                                                         |  |
| Congenital, familial and genetic disorders<br>Craniotabes<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Dacryostenosis congenital<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Brachycephaly<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Cryptorchism<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Ventricular septal defect | 0 / 249 (0.00%)<br>0<br><br>0 / 249 (0.00%)<br>0<br><br>0 / 249 (0.00%)<br>0<br><br>0 / 249 (0.00%)<br>0<br><br>0 / 249 (0.00%)<br>0 | 0 / 250 (0.00%)<br>0<br><br>0 / 250 (0.00%)<br>0<br><br>0 / 250 (0.00%)<br>0<br><br>0 / 250 (0.00%)<br>0 |  |

|                                                                                                                                                                                                                                                                                        |                                                  |                                                  |  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|--------------------------------------------------|--|
| alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                         | 0 / 249 (0.00%)<br>0                             | 0 / 250 (0.00%)<br>0                             |  |
| Cardiac disorders<br>Aortic valve incompetence<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Tricuspid valve incompetence<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all) | 0 / 249 (0.00%)<br>0<br><br>0 / 249 (0.00%)<br>0 | 0 / 250 (0.00%)<br>0<br><br>0 / 250 (0.00%)<br>0 |  |
| Nervous system disorders<br>Hypertonia<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Hypotonia<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                            | 0 / 249 (0.00%)<br>0<br><br>0 / 249 (0.00%)<br>0 | 0 / 250 (0.00%)<br>0<br><br>0 / 250 (0.00%)<br>0 |  |
| Blood and lymphatic system disorders<br>Anaemia<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Iron deficiency anaemia<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)     | 0 / 249 (0.00%)<br>0<br><br>0 / 249 (0.00%)<br>0 | 0 / 250 (0.00%)<br>0<br><br>0 / 250 (0.00%)<br>0 |  |
| Eye disorders<br>Conjunctivitis<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                      | 0 / 249 (0.00%)<br>0                             | 0 / 250 (0.00%)<br>0                             |  |
| Gastrointestinal disorders                                                                                                                                                                                                                                                             |                                                  |                                                  |  |

|                              |                 |                 |  |
|------------------------------|-----------------|-----------------|--|
| Diarrhoea                    |                 |                 |  |
| alternative assessment type: |                 |                 |  |
| Systematic                   |                 |                 |  |
| subjects affected / exposed  | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)            | 0               | 0               |  |
| Vomiting                     |                 |                 |  |
| alternative assessment type: |                 |                 |  |
| Systematic                   |                 |                 |  |
| subjects affected / exposed  | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)            | 0               | 0               |  |
| Abdominal pain               |                 |                 |  |
| alternative assessment type: |                 |                 |  |
| Systematic                   |                 |                 |  |
| subjects affected / exposed  | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)            | 0               | 0               |  |
| Haematochezia                |                 |                 |  |
| alternative assessment type: |                 |                 |  |
| Systematic                   |                 |                 |  |
| subjects affected / exposed  | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)            | 0               | 0               |  |
| Abdominal distension         |                 |                 |  |
| alternative assessment type: |                 |                 |  |
| Systematic                   |                 |                 |  |
| subjects affected / exposed  | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)            | 0               | 0               |  |
| Aphthous stomatitis          |                 |                 |  |
| alternative assessment type: |                 |                 |  |
| Systematic                   |                 |                 |  |
| subjects affected / exposed  | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)            | 0               | 0               |  |
| Constipation                 |                 |                 |  |
| alternative assessment type: |                 |                 |  |
| Systematic                   |                 |                 |  |
| subjects affected / exposed  | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)            | 0               | 0               |  |
| Dyspepsia                    |                 |                 |  |
| alternative assessment type: |                 |                 |  |
| Systematic                   |                 |                 |  |
| subjects affected / exposed  | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)            | 0               | 0               |  |
| Infantile colic              |                 |                 |  |
| alternative assessment type: |                 |                 |  |
| Systematic                   |                 |                 |  |

|                                            |                 |                 |  |
|--------------------------------------------|-----------------|-----------------|--|
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)                          | 0               | 0               |  |
| Umbilical hernia                           |                 |                 |  |
| alternative assessment type:<br>Systematic |                 |                 |  |
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)                          | 0               | 0               |  |
| Gastrooesophageal reflux disease           |                 |                 |  |
| alternative assessment type:<br>Systematic |                 |                 |  |
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)                          | 0               | 0               |  |
| Stomatitis                                 |                 |                 |  |
| alternative assessment type:<br>Systematic |                 |                 |  |
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)                          | 0               | 0               |  |
| Skin and subcutaneous tissue disorders     |                 |                 |  |
| Dermatitis atopic                          |                 |                 |  |
| alternative assessment type:<br>Systematic |                 |                 |  |
| subjects affected / exposed                | 0 / 249 (0.00%) | 1 / 250 (0.40%) |  |
| occurrences (all)                          | 0               | 1               |  |
| Dermatitis allergic                        |                 |                 |  |
| alternative assessment type:<br>Systematic |                 |                 |  |
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)                          | 0               | 0               |  |
| Rash                                       |                 |                 |  |
| alternative assessment type:<br>Systematic |                 |                 |  |
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)                          | 0               | 0               |  |
| Dermatitis                                 |                 |                 |  |
| alternative assessment type:<br>Systematic |                 |                 |  |
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)                          | 0               | 0               |  |
| Dermatitis diaper                          |                 |                 |  |
| alternative assessment type:<br>Systematic |                 |                 |  |

|                                                            |                                                                                                                                                                                                                                                                                  |                 |  |
|------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--|
| subjects affected / exposed                                | 0 / 249 (0.00%)                                                                                                                                                                                                                                                                  | 0 / 250 (0.00%) |  |
| occurrences (all)                                          | 0                                                                                                                                                                                                                                                                                | 0               |  |
| Heat rash                                                  |                                                                                                                                                                                                                                                                                  |                 |  |
| alternative assessment type:<br>Systematic                 |                                                                                                                                                                                                                                                                                  |                 |  |
| subjects affected / exposed                                | 0 / 249 (0.00%)                                                                                                                                                                                                                                                                  | 0 / 250 (0.00%) |  |
| occurrences (all)                                          | 0                                                                                                                                                                                                                                                                                | 0               |  |
| Dermatitis contact                                         |                                                                                                                                                                                                                                                                                  |                 |  |
| alternative assessment type:<br>Systematic                 |                                                                                                                                                                                                                                                                                  |                 |  |
| subjects affected / exposed                                | 0 / 249 (0.00%)                                                                                                                                                                                                                                                                  | 0 / 250 (0.00%) |  |
| occurrences (all)                                          | 0                                                                                                                                                                                                                                                                                | 0               |  |
| Hyperhidrosis                                              |                                                                                                                                                                                                                                                                                  |                 |  |
| alternative assessment type:<br>Systematic                 |                                                                                                                                                                                                                                                                                  |                 |  |
| subjects affected / exposed                                | 0 / 249 (0.00%)                                                                                                                                                                                                                                                                  | 0 / 250 (0.00%) |  |
| occurrences (all)                                          | 0                                                                                                                                                                                                                                                                                | 0               |  |
| Seborrhoeic dermatitis                                     |                                                                                                                                                                                                                                                                                  |                 |  |
| alternative assessment type:<br>Systematic                 |                                                                                                                                                                                                                                                                                  |                 |  |
| subjects affected / exposed                                | 0 / 249 (0.00%)                                                                                                                                                                                                                                                                  | 0 / 250 (0.00%) |  |
| occurrences (all)                                          | 0                                                                                                                                                                                                                                                                                | 0               |  |
| Skin inflammation                                          |                                                                                                                                                                                                                                                                                  |                 |  |
| alternative assessment type:<br>Systematic                 |                                                                                                                                                                                                                                                                                  |                 |  |
| subjects affected / exposed                                | 0 / 249 (0.00%)                                                                                                                                                                                                                                                                  | 0 / 250 (0.00%) |  |
| occurrences (all)                                          | 0                                                                                                                                                                                                                                                                                | 0               |  |
| Urticaria                                                  |                                                                                                                                                                                                                                                                                  |                 |  |
| alternative assessment type:<br>Systematic                 |                                                                                                                                                                                                                                                                                  |                 |  |
| subjects affected / exposed                                | 0 / 249 (0.00%)                                                                                                                                                                                                                                                                  | 0 / 250 (0.00%) |  |
| occurrences (all)                                          | 0                                                                                                                                                                                                                                                                                | 0               |  |
| Tenderness (Any): Infant Series<br>Dose 1 and Toddler Dose | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                 |  |
| alternative dictionary used: Local<br>Reactions 0.0        |                                                                                                                                                                                                                                                                                  |                 |  |
| alternative assessment type:<br>Systematic                 |                                                                                                                                                                                                                                                                                  |                 |  |
| subjects affected / exposed <sup>[19]</sup>                | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%)   |  |
| occurrences (all)                                          | 0                                                                                                                                                                                                                                                                                | 0               |  |
| Tenderness (Any): Infant Series<br>Dose 2                  | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |                 |  |

|                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                         |                               |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--|
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[20]</sup></p> <p>occurrences (all)</p> | <p>0 / 1 (0.00%)</p> <p>0</p>                                                                                                                                                                                                                                                           | <p>0 / 1 (0.00%)</p> <p>0</p> |  |
| <p>Tenderness (Any): Infant Series Dose 3</p>                                                                                                                                     | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                               |  |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[21]</sup></p> <p>occurrences (all)</p> | <p>0 / 1 (0.00%)</p> <p>0</p>                                                                                                                                                                                                                                                           | <p>0 / 1 (0.00%)</p> <p>0</p> |  |
| <p>Tenderness (significant): Infant Series Dose 1 and Toddler Dose</p>                                                                                                            | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                               |  |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[22]</sup></p> <p>occurrences (all)</p> | <p>0 / 1 (0.00%)</p> <p>0</p>                                                                                                                                                                                                                                                           | <p>0 / 1 (0.00%)</p> <p>0</p> |  |
| <p>Tenderness (significant): Infant Series Dose 2</p>                                                                                                                             | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                               |  |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[23]</sup></p> <p>occurrences (all)</p> | <p>0 / 1 (0.00%)</p> <p>0</p>                                                                                                                                                                                                                                                           | <p>0 / 1 (0.00%)</p> <p>0</p> |  |
| <p>Tenderness (significant): Infant Series Dose 3</p>                                                                                                                             | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                               |  |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[24]</sup></p> <p>occurrences (all)</p> | <p>0 / 1 (0.00%)</p> <p>0</p>                                                                                                                                                                                                                                                           | <p>0 / 1 (0.00%)</p> <p>0</p> |  |
| <p>Induration (Any): Infant Series Dose 1 and Toddler Dose</p>                                                                                                                    | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.</p> |                               |  |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p>                                                                            |                                                                                                                                                                                                                                                                                         |                               |  |

|                                                              |                                                                                                                                                                                                                                                                                  |               |  |
|--------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|--|
| subjects affected / exposed <sup>[25]</sup>                  | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%) |  |
| occurrences (all)                                            | 0                                                                                                                                                                                                                                                                                | 0             |  |
| Induration (Any): Infant Series Dose 2                       | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |               |  |
| alternative dictionary used: Local Reactions 0.0             |                                                                                                                                                                                                                                                                                  |               |  |
| alternative assessment type: Systematic                      |                                                                                                                                                                                                                                                                                  |               |  |
| subjects affected / exposed <sup>[26]</sup>                  | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%) |  |
| occurrences (all)                                            | 0                                                                                                                                                                                                                                                                                | 0             |  |
| Induration (Any): Infant Series Dose 3                       | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |               |  |
| alternative dictionary used: Local Reactions 0.0             |                                                                                                                                                                                                                                                                                  |               |  |
| alternative assessment type: Systematic                      |                                                                                                                                                                                                                                                                                  |               |  |
| subjects affected / exposed <sup>[27]</sup>                  | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%) |  |
| occurrences (all)                                            | 0                                                                                                                                                                                                                                                                                | 0             |  |
| Induration (mild): Infant Series Dose 1 and Toddler Dose     | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |               |  |
| alternative dictionary used: Local Reactions 0.0             |                                                                                                                                                                                                                                                                                  |               |  |
| alternative assessment type: Systematic                      |                                                                                                                                                                                                                                                                                  |               |  |
| subjects affected / exposed <sup>[28]</sup>                  | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%) |  |
| occurrences (all)                                            | 0                                                                                                                                                                                                                                                                                | 0             |  |
| Induration (mild): Infant Series Dose 2                      | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |               |  |
| alternative dictionary used: Local Reactions 0.0             |                                                                                                                                                                                                                                                                                  |               |  |
| alternative assessment type: Systematic                      |                                                                                                                                                                                                                                                                                  |               |  |
| subjects affected / exposed <sup>[29]</sup>                  | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%) |  |
| occurrences (all)                                            | 0                                                                                                                                                                                                                                                                                | 0             |  |
| Induration (mild): Infant Series Dose 3                      | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |               |  |
| alternative dictionary used: Local Reactions 0.0             |                                                                                                                                                                                                                                                                                  |               |  |
| alternative assessment type: Systematic                      |                                                                                                                                                                                                                                                                                  |               |  |
| subjects affected / exposed <sup>[30]</sup>                  | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%) |  |
| occurrences (all)                                            | 0                                                                                                                                                                                                                                                                                | 0             |  |
| Induration (moderate): Infant Series Dose 1 and Toddler Dose | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |               |  |

|                                                                                                                                                                                                                                                |               |               |                                                                                                                                                                                                                                                                                  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|---------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[31]</sup></p> <p>occurrences (all)</p>                                                              | 0 / 1 (0.00%) | 0 / 1 (0.00%) |                                                                                                                                                                                                                                                                                  |
| <p>Induration (moderate): Infant Series Dose 2</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[32]</sup></p> <p>occurrences (all)</p>           | 0 / 1 (0.00%) | 0 / 1 (0.00%) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |
| <p>Induration (moderate): Infant Series Dose 3</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[33]</sup></p> <p>occurrences (all)</p>           | 0 / 1 (0.00%) | 0 / 1 (0.00%) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |
| <p>Erythema (Any): Infant Series Dose 1 and Toddler Dose</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[34]</sup></p> <p>occurrences (all)</p> | 0 / 1 (0.00%) | 0 / 1 (0.00%) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |
| <p>Erythema (Any): Infant Series Dose 2</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[35]</sup></p> <p>occurrences (all)</p>                  | 0 / 1 (0.00%) | 0 / 1 (0.00%) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |
| <p>Erythema (Any): Infant Series Dose 3</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p>                                                                                             |               |               | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |

|                                                            |                                                                                                                                                                                                                                                                                  |               |  |
|------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|--|
| subjects affected / exposed <sup>[36]</sup>                | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%) |  |
| occurrences (all)                                          | 0                                                                                                                                                                                                                                                                                | 0             |  |
| Erythema (Mild): Infant Series Dose 1 and Toddler Dose     | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |               |  |
| alternative dictionary used: Local Reactions 0.0           |                                                                                                                                                                                                                                                                                  |               |  |
| alternative assessment type: Systematic                    |                                                                                                                                                                                                                                                                                  |               |  |
| subjects affected / exposed <sup>[37]</sup>                | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%) |  |
| occurrences (all)                                          | 0                                                                                                                                                                                                                                                                                | 0             |  |
| Erythema (Mild): Infant Series Dose 2                      | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |               |  |
| alternative dictionary used: Local Reactions 0.0           |                                                                                                                                                                                                                                                                                  |               |  |
| alternative assessment type: Systematic                    |                                                                                                                                                                                                                                                                                  |               |  |
| subjects affected / exposed <sup>[38]</sup>                | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%) |  |
| occurrences (all)                                          | 0                                                                                                                                                                                                                                                                                | 0             |  |
| Erythema (Mild): Infant Series Dose 3                      | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |               |  |
| alternative dictionary used: Local Reactions 0.0           |                                                                                                                                                                                                                                                                                  |               |  |
| alternative assessment type: Systematic                    |                                                                                                                                                                                                                                                                                  |               |  |
| subjects affected / exposed <sup>[39]</sup>                | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%) |  |
| occurrences (all)                                          | 0                                                                                                                                                                                                                                                                                | 0             |  |
| Erythema (Moderate): Infant Series Dose 1 and Toddler Dose | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |               |  |
| alternative dictionary used: Local Reactions 0.0           |                                                                                                                                                                                                                                                                                  |               |  |
| alternative assessment type: Systematic                    |                                                                                                                                                                                                                                                                                  |               |  |
| subjects affected / exposed <sup>[40]</sup>                | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%) |  |
| occurrences (all)                                          | 0                                                                                                                                                                                                                                                                                | 0             |  |
| Erythema (Moderate): Infant Series Dose 2                  | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |               |  |
| alternative dictionary used: Local Reactions 0.0           |                                                                                                                                                                                                                                                                                  |               |  |
| alternative assessment type: Systematic                    |                                                                                                                                                                                                                                                                                  |               |  |
| subjects affected / exposed <sup>[41]</sup>                | 0 / 1 (0.00%)                                                                                                                                                                                                                                                                    | 0 / 1 (0.00%) |  |
| occurrences (all)                                          | 0                                                                                                                                                                                                                                                                                | 0             |  |
| Erythema (Moderate): Infant Series Dose 3                  | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version. |               |  |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                          |                                                                                                                                                                 |  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[42]</sup></p> <p>occurrences (all)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <p>0 / 1 (0.00%)</p> <p>0</p>                                                                                                                                                                                                                                                            | <p>0 / 1 (0.00%)</p> <p>0</p>                                                                                                                                   |  |
| <p>Erythema (Severe): Infant Series Dose 1 and Toddler Dose</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[43]</sup></p> <p>occurrences (all)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <p>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.</p> |                                                                                                                                                                 |  |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[43]</sup></p> <p>occurrences (all)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <p>0 / 1 (0.00%)</p> <p>0</p>                                                                                                                                                                                                                                                            | <p>0 / 1 (0.00%)</p> <p>0</p>                                                                                                                                   |  |
| <p>Infections and infestations</p> <p>Bronchitis</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Rhinitis</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Pharyngitis</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Upper respiratory tract infection</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Nasopharyngitis</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Respiratory tract infection</p> <p>alternative assessment type: Systematic</p> | <p>0 / 249 (0.00%)</p> <p>0</p> <p>0 / 249 (0.00%)</p> <p>0</p> <p>0 / 249 (0.00%)</p> <p>0</p> <p>0 / 249 (0.00%)</p> <p>0</p> <p>0 / 249 (0.00%)</p> <p>0</p> <p>0 / 249 (0.00%)</p> <p>0</p>                                                                                          | <p>0 / 250 (0.00%)</p> <p>0</p> <p>0 / 250 (0.00%)</p> <p>0</p> <p>0 / 250 (0.00%)</p> <p>0</p> <p>0 / 250 (0.00%)</p> <p>0</p> <p>0 / 250 (0.00%)</p> <p>0</p> |  |

|                                            |                 |                 |
|--------------------------------------------|-----------------|-----------------|
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all)                          | 0               | 0               |
| Urinary tract infection                    |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all)                          | 0               | 0               |
| Bronchopneumonia                           |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all)                          | 0               | 0               |
| Pneumonia                                  |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all)                          | 0               | 0               |
| Viral infection                            |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all)                          | 0               | 0               |
| Ear infection                              |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all)                          | 0               | 0               |
| Gastroenteritis                            |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all)                          | 0               | 0               |
| Laryngitis                                 |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all)                          | 0               | 0               |
| Otitis media                               |                 |                 |
| alternative assessment type:<br>Systematic |                 |                 |
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all)                          | 0               | 0               |

|                                         |                 |                 |  |
|-----------------------------------------|-----------------|-----------------|--|
| Exanthema subitum                       |                 |                 |  |
| alternative assessment type:            |                 |                 |  |
| Systematic                              |                 |                 |  |
| subjects affected / exposed             | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)                       | 0               | 0               |  |
| Viral upper respiratory tract infection |                 |                 |  |
| alternative assessment type:            |                 |                 |  |
| Systematic                              |                 |                 |  |
| subjects affected / exposed             | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)                       | 0               | 0               |  |
| Candidiasis                             |                 |                 |  |
| alternative assessment type:            |                 |                 |  |
| Systematic                              |                 |                 |  |
| subjects affected / exposed             | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)                       | 0               | 0               |  |
| Conjunctivitis infective                |                 |                 |  |
| alternative assessment type:            |                 |                 |  |
| Systematic                              |                 |                 |  |
| subjects affected / exposed             | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)                       | 0               | 0               |  |
| Gastroenteritis staphylococcal          |                 |                 |  |
| alternative assessment type:            |                 |                 |  |
| Systematic                              |                 |                 |  |
| subjects affected / exposed             | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)                       | 0               | 0               |  |
| Oral candidiasis                        |                 |                 |  |
| alternative assessment type:            |                 |                 |  |
| Systematic                              |                 |                 |  |
| subjects affected / exposed             | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)                       | 0               | 0               |  |
| Perianal abscess                        |                 |                 |  |
| alternative assessment type:            |                 |                 |  |
| Systematic                              |                 |                 |  |
| subjects affected / exposed             | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)                       | 0               | 0               |  |
| Pneumonia primary atypical              |                 |                 |  |
| alternative assessment type:            |                 |                 |  |
| Systematic                              |                 |                 |  |
| subjects affected / exposed             | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)                       | 0               | 0               |  |
| Tinea cruris                            |                 |                 |  |
| alternative assessment type:            |                 |                 |  |
| Systematic                              |                 |                 |  |

|                                            |                 |                 |  |
|--------------------------------------------|-----------------|-----------------|--|
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)                          | 0               | 0               |  |
| Tonsillitis                                |                 |                 |  |
| alternative assessment type:<br>Systematic |                 |                 |  |
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)                          | 0               | 0               |  |
| Varicella                                  |                 |                 |  |
| alternative assessment type:<br>Systematic |                 |                 |  |
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)                          | 0               | 0               |  |
| Viral diarrhoea                            |                 |                 |  |
| alternative assessment type:<br>Systematic |                 |                 |  |
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)                          | 0               | 0               |  |
| Viral rash                                 |                 |                 |  |
| alternative assessment type:<br>Systematic |                 |                 |  |
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)                          | 0               | 0               |  |
| Hordeolum                                  |                 |                 |  |
| alternative assessment type:<br>Systematic |                 |                 |  |
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)                          | 0               | 0               |  |
| Acute tonsillitis                          |                 |                 |  |
| alternative assessment type:<br>Systematic |                 |                 |  |
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)                          | 0               | 0               |  |
| Influenza                                  |                 |                 |  |
| alternative assessment type:<br>Systematic |                 |                 |  |
| subjects affected / exposed                | 0 / 249 (0.00%) | 0 / 250 (0.00%) |  |
| occurrences (all)                          | 0               | 0               |  |
| Metabolism and nutrition disorders         |                 |                 |  |
| Weight gain poor                           |                 |                 |  |
| alternative assessment type:<br>Systematic |                 |                 |  |



[32] - 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.

[33] - 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.

[34] - 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.

[35] - 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.

[36] - 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.

[37] - 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.

[38] - 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.

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[39] - 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.

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[40] - 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.

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[41] - 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.

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[42] - 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.

[43] - 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                                                                                                                                                                                                             |
|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 03 July 2006 | HBVAXPRO vaccine (not available for purchase) was replaced with Engerix-B vaccine and meningitis C vaccine was allowed to be given 14 days before study vaccination or after the post vaccination observation period. |

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported