



Clinical trial results:

A Phase 3, Randomized, Active-Controlled, Double-blind Trial Evaluating the Safety, Tolerability and Immunogenicity of a 13-valent Pneumococcal Conjugate Vaccine in Healthy Infants Given With a Meningococcal C-Tetanus Toxoid Conjugate Vaccine and Other Routine Pediatric Vaccinations in Spain.

Summary

EudraCT number	2007-000304-32
Trial protocol	ES
Global end of trial date	23 March 2009

Results information

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

Trial information

Trial identification

Sponsor protocol code	6096A1-3007
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00474539
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 1 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 1 800-718-1021, 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?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	22 July 2009
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	23 March 2009
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that the immune response induced by NeisVac-C given with 13vPnC is noninferior to the immune response induced by NeisVac-C given with 7vPnC when measured 1 month after the 2-dose NeisVac-C infant series.

To demonstrate that the immune responses induced by Infanrix hexa given with 13vPnC are noninferior to the immune responses induced by Infanrix hexa given with 7vPnC when measured 1 month after the 3-dose infant series.

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	04 July 2007
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	Spain: 449
Worldwide total number of subjects	449
EEA total number of subjects	449

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	449

months)	
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 Spain from 4 July 2007 to 23 July 2007.

Pre-assignment

Screening details:

Subjects were enrolled into the study according to the 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, Subject, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	13vPnC Infant Series

Arm description:

Included subjects who received 13-valent pneumococcal conjugate vaccine (13vPnC) coadministered with meningococcal C-tetanus toxoid conjugate vaccine (NeisVac-C) and combined diphtheria-tetanus-acellular pertussis (DTPa), hepatitis B, inactivated poliovirus, and Hemophilus influenzae type b (Hib) vaccine (Infanrix hexa) at the 2- and 4-month visits (infant series dose 2) and one single 0.5 mL dose of 13vPnC coadministered with Infanrix hexa at the 6-month visit (infant series dose 3).

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

Dosage and administration details:

Subjects received one single 0.5 milliliter (mL) dose of 13-valent pneumococcal conjugate vaccine (13vPnC) at the 2-, 4- and 6-month visits.

Investigational medicinal product name	NeisVac-C
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received one single dose of Neisseria meningitidis group C polysaccharide tetanus toxoid conjugated vaccine (NeisVac-C) at the 2- and 4-month visits.

Investigational medicinal product name	Infanrix hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received one single dose of combined diphtheria--tetanus--acellular pertussis (DTPa), hepatitis B, inactivated poliovirus, and hemophilus influenza type b (Hib) vaccine (Infanrix hexa) at the 2-, 4- and 6-month visits.

Arm title	7vPnC Infant Series
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Arm description:

Included subjects who received one single 0.5 mL dose of 7-valent pneumococcal conjugate vaccine (7vPnC) coadministered with meningococcal C-tetanus toxoid conjugate vaccine (NeisVac-C) and combined diphtheria-tetanus-acellular pertussis (DTPa), hepatitis B, inactivated poliovirus, and hemophilus influenza type b (Hib) vaccine (Infanrix hexa) at the 2- and 4-month visits (infant series Dose 2) and one single 0.5 mL dose of 7vPnC coadministered with Infanrix hexa at the 6-month visit (infant series dose 3). One subject was randomized to 7vPnC, but received 13vPnC.

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

Dosage and administration details:

Subjects received one single 0.5 mL dose of 7-valent pneumococcal conjugate vaccine (7vPnC) at the 2-, 4- and 6-month visits.

Investigational medicinal product name	Infanrix hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received one single dose of Infanrix hexa at the 2-, 4- and 6-month visits.

Investigational medicinal product name	NeisVac-C
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received one single dose of NeisVac-C at the 2- and 4-month visits.

Number of subjects in period 1	13vPnC Infant Series	7vPnC Infant Series
Started	223	226
Vaccinated Dose 1	218	226
Vaccinated Dose 3	214	221
Vaccinated Dose 2	217	222
Completed	213	220
Not completed	10	6
Consent withdrawn by subject	3	4
'Randomization error '	5	-
Lost to follow-up	2	1
'Protocol violation '	-	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
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Arm title	13vPnC After Infant Series
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Arm description:

Included subjects who received 13vPnC coadministered with meningococcal C-tetanus toxoid conjugate vaccine (NeisVac-C) and combined diphtheria-tetanus-acellular pertussis (DTPa), hepatitis B, inactivated poliovirus, and hemophilus influenza type b (Hib) vaccine (Infanrix hexa) at the 2- and 4-month visits and 13vPnC coadministered with Infanrix hexa at the 6-month visit in infant series.

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

Arm title	7vPnC After Infant Series
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Arm description:

Included subjects who received 7vPnC coadministered with meningococcal C-tetanus toxoid conjugate vaccine (NeisVac-C) and combined diphtheria-tetanus-acellular pertussis (DTPa), hepatitis B, inactivated poliovirus, and hemophilus influenza type b (Hib) vaccine (Infanrix hexa) at the 2- and 4-month visits and 7vPnC coadministered with Infanrix hexa at the 6-month visit in infant series.

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

Number of subjects in period 2	13vPnC After Infant Series	7vPnC After Infant Series
Started	213	220
Completed	209	220
Not completed	4	0
Consent withdrawn by subject	1	-
Lost to follow-up	3	-

Period 3

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

Arms

Are arms mutually exclusive?	Yes
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Arm title	13vPnC Toddler Dose
Arm description: Subjects received 13vPnC coadministered with NeisVac-C and combined DTPa, inactivated poliovirus, and Hib vaccine (Infanrix IPV + Hib) at the 15-month visit (toddler dose). Measles, mumps, and rubella vaccine (MMR) was administered without study vaccine at the 12-month visit.	
Arm type	Experimental
Investigational medicinal product name	13vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details: Subjects received one single 0.5 mL dose of 13vPnC at the 15-month visit (toddler dose).	
Investigational medicinal product name	Infanrix IPV + Hib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details: Subjects received a single dose of combined DTPa, inactivated poliovirus, and Hib vaccine (Infanrix IPV + Hib) at the 15 month- visit (toddler dose).	
Investigational medicinal product name	MMR
Investigational medicinal product code	
Other name	Priorix
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: Subject received a single dose of Measles, mumps, and rubella vaccine (MMR) without study vaccine at the 12-month visit.	
Investigational medicinal product name	NeisVac-C
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details: Subjects received a single dose of NeisVac-C at the 15-month visit (toddler dose).	
Arm title	7vPnC Toddler Dose
Arm description: Subjects received 7vPnC coadministered with NeisVac-C and combined DTPa, inactivated poliovirus and Hib vaccine (Infanrix IPV + Hib) at the 15-month visit (toddler dose). MMR was administered without study vaccine at the 12-month visit.	
Arm type	Active comparator
Investigational medicinal product name	7vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details: Subjects received one single 0.5 mL dose of 7vPnC at the 15-month visit (toddler dose).	
Investigational medicinal product name	NeisVac-C
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection

Routes of administration	Intramuscular use
Dosage and administration details:	
Subjects received a single dose of NeisVac-C at the 15-month visit (toddler dose).	
Investigational medicinal product name	Infanrix IPV + Hib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Subjects received a single dose of Infanrix IPV + Hib at the 15 month- visit (toddler dose).	
Investigational medicinal product name	MMR
Investigational medicinal product code	
Other name	Priorix
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
Subject received a single dose of MMR without study vaccine at the 12-month visit.	

Number of subjects in period 3	13vPnC Toddler Dose	7vPnC Toddler Dose
Started	209	220
Completed	208	220
Not completed	1	0
'Protocol violation '	1	-

Baseline characteristics

Reporting groups

Reporting group title	13vPnC Infant Series
Reporting group description:	
Included subjects who received 13-valent pneumococcal conjugate vaccine (13vPnC) coadministered with meningococcal C-tetanus toxoid conjugate vaccine (NeisVac-C) and combined diphtheria-tetanus-acellular pertussis (DTPa), hepatitis B, inactivated poliovirus, and Hemophilus influenzae type b (Hib) vaccine (Infanrix hexa) at the 2- and 4-month visits (infant series dose 2) and one single 0.5 mL dose of 13vPnC coadministered with Infanrix hexa at the 6-month visit (infant series dose 3).	
Reporting group title	7vPnC Infant Series
Reporting group description:	
Included subjects who received one single 0.5 mL dose of 7-valent pneumococcal conjugate vaccine (7vPnC) coadministered with meningococcal C-tetanus toxoid conjugate vaccine (NeisVac-C) and combined diphtheria-tetanus-acellular pertussis (DTPa), hepatitis B, inactivated poliovirus, and hemophilus influenza type b (Hib) vaccine (Infanrix hexa) at the 2- and 4-month visits (infant series Dose 2) and one single 0.5 mL dose of 7vPnC coadministered with Infanrix hexa at the 6-month visit (infant series dose 3). One subject was randomized to 7vPnC, but received 13vPnC.	

Reporting group values	13vPnC Infant Series	7vPnC Infant Series	Total
Number of subjects	223	226	449
Age categorical Units: Subjects			
Age continuous			
Total 449 subjects were randomly assigned to the study, 4 subjects were counted twice and 1 subject was found ineligible for the study and was withdrawn before treatment. Only 444 subjects were evaluable for baseline characteristics measure (age continuous).			
Units: months			
arithmetic mean	2.1	2	
standard deviation	± 0.4	± 0.4	-
Gender categorical Units: Subjects			
Female	104	116	220
Male	115	109	224
Other	4	1	5

End points

End points reporting groups

Reporting group title	13vPnC Infant Series
Reporting group description:	
Included subjects who received 13-valent pneumococcal conjugate vaccine (13vPnC) coadministered with meningococcal C-tetanus toxoid conjugate vaccine (NeisVac-C) and combined diphtheria-tetanus-acellular pertussis (DTPa), hepatitis B, inactivated poliovirus, and Hemophilus influenzae type b (Hib) vaccine (Infanrix hexa) at the 2- and 4-month visits (infant series dose 2) and one single 0.5 mL dose of 13vPnC coadministered with Infanrix hexa at the 6-month visit (infant series dose 3).	
Reporting group title	7vPnC Infant Series
Reporting group description:	
Included subjects who received one single 0.5 mL dose of 7-valent pneumococcal conjugate vaccine (7vPnC) coadministered with meningococcal C-tetanus toxoid conjugate vaccine (NeisVac-C) and combined diphtheria-tetanus-acellular pertussis (DTPa), hepatitis B, inactivated poliovirus, and hemophilus influenza type b (Hib) vaccine (Infanrix hexa) at the 2- and 4-month visits (infant series Dose 2) and one single 0.5 mL dose of 7vPnC coadministered with Infanrix hexa at the 6-month visit (infant series dose 3). One subject was randomized to 7vPnC, but received 13vPnC.	
Reporting group title	13vPnC After Infant Series
Reporting group description:	
Included subjects who received 13vPnC coadministered with meningococcal C-tetanus toxoid conjugate vaccine (NeisVac-C) and combined diphtheria-tetanus-acellular pertussis (DTPa), hepatitis B, inactivated poliovirus, and hemophilus influenza type b (Hib) vaccine (Infanrix hexa) at the 2- and 4-month visits and 13vPnC coadministered with Infanrix hexa at the 6-month visit in infant series.	
Reporting group title	7vPnC After Infant Series
Reporting group description:	
Included subjects who received 7vPnC coadministered with meningococcal C-tetanus toxoid conjugate vaccine (NeisVac-C) and combined diphtheria-tetanus-acellular pertussis (DTPa), hepatitis B, inactivated poliovirus, and hemophilus influenza type b (Hib) vaccine (Infanrix hexa) at the 2- and 4-month visits and 7vPnC coadministered with Infanrix hexa at the 6-month visit in infant series.	
Reporting group title	13vPnC Toddler Dose
Reporting group description:	
Subjects received 13vPnC coadministered with NeisVac-C and combined DTPa, inactivated poliovirus, and Hib vaccine (Infanrix IPV + Hib) at the 15-month visit (toddler dose). Measles, mumps, and rubella vaccine (MMR) was administered without study vaccine at the 12-month visit.	
Reporting group title	7vPnC Toddler Dose
Reporting group description:	
Subjects received 7vPnC coadministered with NeisVac-C and combined DTPa, inactivated poliovirus and Hib vaccine (Infanrix IPV + Hib) at the 15-month visit (toddler dose). MMR was administered without study vaccine at the 12-month visit.	
Subject analysis set title	13vPnC After Infant Series Dose 2
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Subjects received one single 0.5 mL dose of 13vPnC coadministered with NeisVac-C and Infanrix hexa at the 2- and 4-month visits (infant series Dose 2).	
Subject analysis set title	7vPnC After Infant Series Dose 2
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Subjects received one single 0.5 mL dose of 7vPnC coadministered with NeisVac-C and Infanrix hexa at the 2- and 4-month visits (infant series Dose 2).	
Subject analysis set title	13vPnC After Infant Series Dose 3
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Subjects received one single 0.5 mL dose of 13vPnC coadministered with Infanrix hexa at the 6-month visit (infant series dose 3).	
Subject analysis set title	7vPnC After Infant Series Dose 3
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received one single 0.5 mL dose of 7vPnC coadministered with Infanrix hexa at the 6-month visit (infant series dose 3).

Subject analysis set title	7vPnC Dose 1
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one single 0.5 mL dose of 7vPnC coadministered with NeisVac-C and Infanrix hexa at the 2-month visit.

Subject analysis set title	13vPnC Dose 1
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one single 0.5 mL dose of 13vPnC coadministered with NeisVac-C and Infanrix hexa at the 2-month visit.

Subject analysis set title	13vPnC Dose 2
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one single 0.5 mL dose of 13vPnC coadministered with NeisVac-C and Infanrix hexa at the 4-month visit.

Subject analysis set title	7vPnC Dose 2
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one single 0.5 mL dose of 7vPnC coadministered with NeisVac-C and Infanrix hexa at the 4-month visit.

Subject analysis set title	13vPnC Dose 3
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one single 0.5 mL dose of 13vPnC coadministered with Infanrix hexa and at the 6-month visit.

Subject analysis set title	7vPnC Dose 3
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one single 0.5 mL dose of 7vPnC coadministered with Infanrix hexa and at the 6-month visit.

Subject analysis set title	13vPnC Toddler Dose
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one single 0.5 mL dose of 13vPnC coadministered with NeisVac-C and Infanrix-IPV+Hib at the 15-month visit.

Subject analysis set title	7vPnC Toddler Dose
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one single 0.5 mL dose of 7vPnC coadministered with with NeisVac-C and Infanrix-IPV+Hib at the 15-month visit.

Subject analysis set title	13vPnC After Toddler Dose
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received one single 0.5 mL dose of 13vPnC coadministered with NeisVac-C and Infanrix IPV + Hib at the 15-month visit (toddler dose).

Subject analysis set title	7vPnC After Toddler Dose
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received one single 0.5 mL dose of 7vPnC coadministered with NeisVac-C and Infanrix IPV + Hib at the 15-month visit (toddler dose).

Primary: Percentage of Subjects Achieving a Serum Bactericidal Assay (SBA) Titer Greater than or Equal to (\geq) 1:8 in 13vPnC Group Relative to 7vPnC Group After the 2-dose NeisVac-C Infant Series

End point title	Percentage of Subjects Achieving a Serum Bactericidal Assay (SBA) Titer Greater than or Equal to (\geq) 1:8 in 13vPnC Group Relative to 7vPnC Group After the 2-dose NeisVac-C Infant Series
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End point description:

Percentage of subjects achieving a meningococcal C SBA serum antibody titer greater than or equal to (\geq) 1:8 along with the corresponding 95% confidence interval (CI) are presented. Evaluable immunogenicity (per protocol) population consisting of eligible subjects who adhered to protocol requirements, had valid and determinate assay results, and had no other major protocol violations.

End point type	Primary
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End point timeframe:

One month after infant series dose (at 5 months of age)

End point values	13vPnC After Infant Series Dose 2	7vPnC After Infant Series Dose 2		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	206	218		
Units: percentage of subjects				
number (confidence interval 95%)	98.5 (95.8 to 99.7)	99.1 (96.7 to 99.9)		

Statistical analyses

Statistical analysis title	SBA titer \geq 1:8 after Infant Series Dose 2
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Statistical analysis description:

For Meningococcal C the difference in percentages between the two groups (13vPnC - 7vPnC) at \geq 1:8 titer was calculated.

Comparison groups	13vPnC After Infant Series Dose 2 v 7vPnC After Infant Series Dose 2
Number of subjects included in analysis	424
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[1]
Parameter estimate	Difference
Point estimate	-0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.3
upper limit	2

Notes:

[1] - Non-inferiority for immune response induced by NeisVac-C was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) greater than ($>$) -10%.

Primary: Geometric Mean Titers (GMT) for Meningococcal C Antibodies in as Measured by Serum Bactericidal Assay (SBA) 13vPnC Group Relative to 7vPnC Group After the 2-dose NeisVac-C Infant Series and the Toddler Dose

End point title	Geometric Mean Titers (GMT) for Meningococcal C Antibodies in
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End point description:

The evaluable 2-dose immunogenicity (per protocol) population was the primary analysis population consisting of eligible subjects who adhered to the protocol requirements, had valid and determinate assay results, and had no other major protocol violations.

End point type Primary

End point timeframe:

One month after infant series dose 2 (at 5 months of age) and one month after toddler dose (at 16 months of age)

End point values	13vPnC After Infant Series Dose 2	7vPnC After Infant Series Dose 2	13vPnC After Toddler Dose	7vPnC After Toddler Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	206	218	164 ^[2]	172
Units: titer				
geometric mean (confidence interval 95%)	654.55 (557.75 to 768.16)	757.04 (648.45 to 883.81)	2573.06 (2176.29 to 3042.16)	2098.12 (1779.65 to 2473.58)

Notes:

[2] - Subjects with determinate immunoglobulin G (IgG) antibody concentration to given vaccine component.

Statistical analyses

Statistical analysis title	GMT ratio after Infant Series Dose 2
Statistical analysis description: For Meningococcal C the GMT ratio (13vPnC/7vPnC) was calculated after the infant series dose 2.	
Comparison groups	7vPnC After Infant Series Dose 2 v 13vPnC After Infant Series Dose 2
Number of subjects included in analysis	424
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[3]
Parameter estimate	Ratio
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.08

Notes:

[3] - Non-inferiority for or immune response induced by NeisVac-C was declared if the lower bound of the 2-sided, 95% CI for the GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Statistical analysis title	GMT ratio after Toddler Dose
Statistical analysis description: For Meningococcal C the GMT ratio (13vPnC/7vPnC) was calculated after the toddler dose.	
Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose

Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[4]
Parameter estimate	Ratio
Point estimate	1.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.97
upper limit	1.55

Notes:

[4] - Non-inferiority for or immune response induced by NeisVac-C was declared if the lower bound of the 2-sided, 95% CI for the GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Primary: Percentage of Subjects Achieving Predefined Antibody Levels for Diphtheria and Tetanus in 13vPnC Group Relative to 7vPnC Group After the 3-dose Infant Series and After the Toddler Dose

End point title	Percentage of Subjects Achieving Predefined Antibody Levels for Diphtheria and Tetanus in 13vPnC Group Relative to 7vPnC Group After the 3-dose Infant Series and After the Toddler Dose
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End point description:

Predefined antibody levels for Diphtheria (0.01 or 0.1 International units [IU]/mL) and Tetanus (0.01 or 0.1 [IU]/mL). The evaluable 3-dose immunogenicity (per protocol) population was the primary analysis population consisting of eligible subjects who adhered to the protocol requirements, had valid and determinate assay results, and had no other major protocol violations.

End point type	Primary
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End point timeframe:

One month after infant series dose 3 (at 7 months of age) and one month after the toddler dose (at 16 months of age)

End point values	13vPnC After Infant Series Dose 3	7vPnC After Infant Series Dose 3	13vPnC After Toddler Dose	7vPnC After Toddler Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	197	212	164	172
Units: percentage of subjects				
number (confidence interval 95%)				
Diphtheria ≥ 0.10 IU/mL	98.5 (95.6 to 99.7)	99.1 (96.6 to 99.9)	100 (97.8 to 100)	100 (97.9 to 100)
Diphtheria ≥ 0.01 IU/mL	100 (98.1 to 100)	100 (98.3 to 100)	100 (97.8 to 100)	100 (97.9 to 100)
Tetanus ≥ 0.10 IU/mL	96.6 (92.6 to 98.7)	96.7 (93 to 98.8)	100 (97.8 to 100)	100 (97.9 to 100)
Tetanus ≥ 0.01 IU/mL	100 (97.9 to 100)	100 (98 to 100)	100 (97.8 to 100)	100 (97.9 to 100)

Statistical analyses

Statistical analysis title	Diphtheria ≥ 0.10 IU/mL:After Infant Series Dose 3
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Statistical analysis description:

For diphtheria the difference in percentage between the two groups (13vPnC - 7vPnC) at ≥ 0.10 IU/mL threshold was calculated.

Comparison groups	13vPnC After Infant Series Dose 3 v 7vPnC After Infant Series Dose 3
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[5]
Parameter estimate	Difference
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.5
upper limit	2

Notes:

[5] - Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $> -10\%$.

Statistical analysis title	Diphtheria ≥ 0.01 IU/mL: After Infant Series Dose 3
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Statistical analysis description:

For diphtheria the difference in percentage between the two groups (13vPnC - 7vPnC) at ≥ 0.010 IU/mL threshold was calculated.

Comparison groups	13vPnC After Infant Series Dose 3 v 7vPnC After Infant Series Dose 3
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[6]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	1.7

Notes:

[6] - Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $> -10\%$.

Statistical analysis title	Tetanus ≥ 0.10 IU/mL: After Infant Series Dose 3
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Statistical analysis description:

For tetanus the difference in percentage between the two groups (13vPnC - 7vPnC) at ≥ 0.10 IU/mL threshold was calculated.

Comparison groups	13vPnC After Infant Series Dose 3 v 7vPnC After Infant Series Dose 3
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[7]
Parameter estimate	Difference
Point estimate	-0.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.4
upper limit	4

Notes:

[7] - Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) > -10%.

Statistical analysis title	Tetanus >=0.01 IU/mL: After Infant Series Dose 3
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Statistical analysis description:

For tetanus the difference in percentage between the two groups (13vPnC - 7vPnC) at >=0.010 IU/mL threshold was calculated.

Comparison groups	13vPnC After Infant Series Dose 3 v 7vPnC After Infant Series Dose 3
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[8]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	2

Notes:

[8] - Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) > -10%.

Statistical analysis title	Diphtheria >=0.10 IU/mL: After Toddler Dose
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Statistical analysis description:

For diphtheria the difference in percentage between the two groups (13vPnC - 7vPnC) at >=0.10 IU/mL threshold was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[9]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.2
upper limit	2.2

Notes:

[9] - Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) > -10%.

Statistical analysis title	Diphtheria >=0.01 IU/mL: After Toddler Dose
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Statistical analysis description:

For diphtheria the difference in percentage between the two groups (13vPnC - 7vPnC) at >=0.010 IU/mL threshold was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
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Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[10]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.2
upper limit	2.2

Notes:

[10] - Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) > -10%.

Statistical analysis title	Tetanus >=0.10 IU/mL: After Toddler Dose
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Statistical analysis description:

For tetanus the difference in percentage between the two groups (13vPnC - 7vPnC) at >=0.10 IU/mL threshold was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[11]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.3
upper limit	2.2

Notes:

[11] - Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) > -10%.

Statistical analysis title	Tetanus >=0.01 IU/mL: After Toddler Dose
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Statistical analysis description:

For tetanus the difference in percentage between the two groups (13vPnC - 7vPnC) at >=0.01 IU/mL threshold was calculated.

Comparison groups	7vPnC After Toddler Dose v 13vPnC After Toddler Dose
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[12]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.3
upper limit	2.2

Notes:

[12] - Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) > -10%.

Primary: Geometric Mean Antibody Concentrations (GMC) for Diphtheria and

Tetanus in 13vPnC Group Relative to 7vPnC Group After the 3-dose Infant Series and After the Toddler Dose

End point title	Geometric Mean Antibody Concentrations (GMC) for Diphtheria and Tetanus in 13vPnC Group Relative to 7vPnC Group After the 3-dose Infant Series and After the Toddler Dose
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End point description:

The evaluable 3-dose immunogenicity (per protocol) population was the primary analysis population consisting of eligible subjects who adhered to the protocol requirements, had valid and determinate assay results, and had no other major protocol violations.

End point type	Primary
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End point timeframe:

One month after infant series dose 3 (at 7 months of age) and one month after the toddler dose (at 16 months of age)

End point values	13vPnC After Infant Series Dose 3	7vPnC After Infant Series Dose 3	13vPnC After Toddler Dose	7vPnC After Toddler Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	197	212	164	172
Units: IU/mL				
geometric mean (confidence interval 95%)				
Diphtheria	0.79 (0.69 to 0.9)	0.92 (0.81 to 1.04)	3 (2.63 to 3.41)	3.23 (2.88 to 3.63)
Tetanus	1.1 (0.94 to 1.27)	1.2 (1.04 to 1.39)	3.29 (2.83 to 3.83)	3.28 (2.83 to 3.79)

Statistical analyses

Statistical analysis title	Diphtheria: After Infant Series Dose 3
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Statistical analysis description:

For diphtheria toxoid the GMC ratio (13vPnC/7vPnC) was calculated after the infant series dose 3.

Comparison groups	13vPnC After Infant Series Dose 3 v 7vPnC After Infant Series Dose 3
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[13]
Parameter estimate	Ratio
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	1.03

Notes:

[13] - Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC ratio (13vPnC group/7vPnC group) was > 0.5 (2-fold criterion).

Statistical analysis title	Tetanus: After Infant Series Dose 3
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Statistical analysis description:

For tetanus the GMC ratio (13vPnC/7vPnC) was calculated.

Comparison groups	13vPnC After Infant Series Dose 3 v 7vPnC After Infant Series Dose 3
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[14]
Parameter estimate	Ratio
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.12

Notes:

[14] - Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC ratio (13vPnC group/7vPnC group) was > 0.5 (2-fold criterion).

Statistical analysis title	Diphtheria: After Toddler Dose
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Statistical analysis description:

For diphtheria toxoid the GMC ratio (13vPnC/7vPnC) was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[15]
Parameter estimate	Ratio
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.1

Notes:

[15] - Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Statistical analysis title	Tetanus: After Toddler Dose
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Statistical analysis description:

For tetanus the GMC ratio (13vPnC/7vPnC) was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[16]
Parameter estimate	Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.24

Notes:

[16] - Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Primary: Percentage of Subjects Achieving Antibody Level \geq 0.35 microgram (μ g)/mL in 13vPnC Group After the Second and the Third Dose of a 3-Dose Infant Series and After the Toddler Dose

End point title	Percentage of Subjects Achieving Antibody Level \geq 0.35 microgram (μ g)/mL in 13vPnC Group After the Second and the Third Dose of a 3-Dose Infant Series and After the Toddler Dose ^[17]
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End point description:

Percentages of subjects achieving World Health Organization (WHO) predefined antibody threshold \geq 0.35 μ g/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. The evaluable immunogenicity (per protocol) population was the primary analysis population consisting of eligible subjects who adhered to the protocol requirements, had valid and determinate assay results, and had no other major protocol violations.

End point type	Primary
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End point timeframe:

One month after infant series dose 2 (at 5 months of age) and dose 3 (at 7 months of age) and one month after the toddler dose (at 16 months of age)

Notes:

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

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

End point values	13vPnC After Infant Series Dose 2	13vPnC After Infant Series Dose 3	13vPnC After Toddler Dose	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	206	197	164	
Units: percentage of subjects				
number (confidence interval 95%)				
Common Serotypes - Serotype 4	27.9 (87.9 to 95.7)	98.5 (95.7 to 99.7)	100 (97.7 to 100)	
Common Serotypes - Serotype 6B	92.5 (21.8 to 34.7)	94.9 (90.9 to 97.5)	100 (97.7 to 100)	
Common Serotypes - Serotype 9V	89.9 (84.8 to 93.7)	97 (93.5 to 98.9)	99.3 (96.3 to 100)	
Common Serotypes - Serotype 14	91 (86.1 to 94.6)	97 (93.6 to 98.9)	99.4 (96.6 to 100)	
Common Serotypes - Serotype 18C	88.9 (83.7 to 92.9)	99 (96.4 to 99.9)	98.8 (95.6 to 99.8)	
Common Serotypes - Serotype 19F	100 (98.2 to 100)	99 (96.4 to 99.9)	98.7 (95.5 to 99.8)	
Common Serotypes - Serotype 23F	55.8 (48.6 to 62.8)	93 (88.5 to 96.1)	98.1 (94.7 to 99.6)	
Additional Serotypes - Serotype 1	96 (92.2 to 98.2)	98.5 (95.7 to 99.7)	98.8 (95.6 to 99.8)	
Additional Serotypes - Serotype 3	73.8 (67.1 to 79.9)	86.2 (80.5 to 90.7)	93.6 (88.6 to 96.9)	
Additional Serotypes - Serotype 5	86.4 (80.8 to 90.8)	96 (92.2 to 98.2)	100 (97.6 to 100)	
Additional Serotypes - Serotype 6A	80.8 (74.6 to 86)	99 (96.4 to 99.9)	99.4 (96.5 to 100)	
Additional Serotypes - Serotype 7F	94.5 (90.3 to 97.2)	100 (98.2 to 100)	99.4 (96.5 to 100)	

Additional Serotypes - Serotype 19A	92.9 (88.4 to 96.1)	99.5 (97.2 to 100)	100 (97.5 to 100)	
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Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Antibody Concentration (GMC) in 13vPnC Group After the Second and the Third Dose of a 3-Dose Infant Series and After the Toddler Dose

End point title	Geometric Mean Antibody Concentration (GMC) in 13vPnC Group After the Second and the Third Dose of a 3-Dose Infant Series and After the Toddler Dose ^[18]
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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. GMCs (13vPnC) were calculated for each pneumococcal serotype and timepoint, and 2-sided, 95% CI were constructed. The evaluable immunogenicity (per protocol) population was the primary analysis population consisting of eligible subjects who adhered to the protocol requirements, had valid and determinate assay results, and had no other major protocol violations.

End point type	Primary
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End point timeframe:

One month after infant series dose 2 (at 5 months of age) and dose 3 (at 7 months of age) and one month after the toddler dose (at 16 months of age)

Notes:

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

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

End point values	13vPnC After Infant Series Dose 2	13vPnC After Infant Series Dose 3	13vPnC After Toddler Dose	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	206	197	164	
Units: µg/mL				
geometric mean (confidence interval 95%)				
Common Serotypes - Serotype 4	1.55 (1.35 to 1.78)	2.32 (2.08 to 2.6)	3.88 (3.42 to 4.4)	
Common Serotypes - Serotype 6B	0.21 (0.18 to 0.25)	2.59 (2.2 to 3.05)	12.25 (10.78 to 13.92)	
Common Serotypes - Serotype 9V	1.15 (1.01 to 1.32)	1.51 (1.35 to 1.68)	2.67 (2.34 to 3.05)	
Common Serotypes - Serotype 14	1.94 (1.64 to 2.29)	4.51 (3.89 to 5.22)	9.82 (8.54 to 11.3)	
Common Serotypes - Serotype 18C	1.3 (1.11 to 1.51)	1.86 (1.68 to 2.07)	2.29 (2.01 to 2.61)	
Common Serotypes - Serotype 19F	2.98 (2.6 to 3.41)	2.46 (2.21 to 2.74)	6.11 (5.21 to 7.16)	
Common Serotypes - Serotype 23F	0.4 (0.34 to 0.48)	1.67 (1.44 to 1.94)	3.96 (3.43 to 4.59)	
Additional Serotypes - Serotype 1	1.87 (1.61 to 2.16)	2.95 (2.61 to 3.33)	4.6 (3.94 to 5.37)	
Additional Serotypes - Serotype 3	0.54 (0.48 to 0.61)	0.85 (0.76 to 0.95)	1.04 (0.91 to 1.19)	

Additional Serotypes - Serotype 5	0.88 (0.77 to 1)	1.83 (1.62 to 2.06)	3.69 (3.26 to 4.18)	
Additional Serotypes - Serotype 6A	0.81 (0.7 to 0.95)	3.08 (2.76 to 3.44)	7.71 (6.75 to 8.8)	
Additional Serotypes - Serotype 7F	1.51 (1.33 to 1.71)	3.41 (3.11 to 3.74)	5.66 (4.9 to 6.53)	
Additional Serotypes - Serotype 19A	1.52 (1.31 to 1.76)	2.5 (2.27 to 2.75)	10.21 (8.92 to 11.68)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving a Serum Bactericidal Assay (SBA) Titer $\geq 1:8$ in 13vPnC Group Relative to 7vPnC Group After the Toddler Dose

End point title	Percentage of Subjects Achieving a Serum Bactericidal Assay (SBA) Titer $\geq 1:8$ in 13vPnC Group Relative to 7vPnC Group After the Toddler Dose
End point description:	Percentage of subjects achieving a meningococcal C SBA serum antibody titer $\geq 1:8$ along with the corresponding 95% CI were presented. Evaluable immunogenicity (per protocol) population consisting of eligible subjects who adhered to the protocol requirements, had valid and determinate assay results, and had no other major protocol violations.
End point type	Secondary
End point timeframe:	One month after toddler dose (at 16 months of age)

End point values	13vPnC After Toddler Dose	7vPnC After Toddler Dose		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	164 ^[19]	172		
Units: percentage of subjects				
number (confidence interval 95%)	100 (97.8 to 100)	99.4 (96.8 to 100)		

Notes:

[19] - Subjects with a determinate IgG antibody concentration to the given concomitant vaccine component.

Statistical analyses

Statistical analysis title	SBA titer $\geq 1:8$ after toddler dose
Statistical analysis description:	For Meningococcal C the difference in percentages between the two groups (13vPnC - 7vPnC) at $\geq 1:8$ titer was calculated.
Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose

Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[20]
Parameter estimate	Difference
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.7
upper limit	3.2

Notes:

[20] - Non-inferiority for immune response induced by NeisVac-C was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) > -10%.

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

End point title	Percentage of Subjects Reporting Pre-Specified Local Reactions
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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 (Sev) (>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
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End point timeframe:

During the 4-day period after each dose

End point values	13vPnC Dose 1	7vPnC Dose 1	13vPnC Dose 2	7vPnC Dose 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	218	226	217	222
Units: percentage of subjects				
number (not applicable)				
Tenderness-Any (n=199,205,182,180,170,175,164,172)	21.1	18.5	21.4	16.1
Tenderness-Sig (n=199,200,177,177,167,169,154,160)	3	4	1.1	4
Swelling-Any (n=196,200,182,177,171,170,169,168)	13.3	14.5	22	14.7
Swelling-Mild (n=196,200,182,177,171,170,166,168)	12.2	13	20.3	13
Swelling-Mod (n=196,196,177,175,166,168,156,163)	2.6	2	2.3	2.3
Swelling-Sev (n=196,196,177,175,166,168,152,156)	0	0	0	0
Redness-Any (n=197,199,181,180,172,172,170,169)	15.2	15.1	23.8	20
Redness-Mild (n=197,198,180,180,172,171,167,165)	14.7	14.1	22.2	19.4
Redness-Mod (n=196,197,178,175,166,169,157,163)	0.5	1	2.2	1.1
Redness-Sev (n=196,196,177,175,166,168,152,156)	0	0	0	0

End point values	13vPnC Dose 3	7vPnC Dose 3	13vPnC Toddler Dose	7vPnC Toddler Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	214	221	209	220
Units: percentage of subjects				
number (not applicable)				
Tenderness-Any (n=199,205,182,180,170,175,164,172)	10.6	14.3	28.7	26.7
Tenderness-Sig (n=199,200,177,177,167,169,154,160)	1.2	1.2	2.6	3.8
Swelling-Any (n=196,200,182,177,171,170,169,168)	23.4	20	26.6	18.5
Swelling-Mild (n=196,200,182,177,171,170,166,168)	20.5	17.1	22.9	16
Swelling-Mod (n=196,196,177,175,166,168,156,163)	6.6	6	9	5.5
Swelling-Sev (n=196,196,177,175,166,168,152,156)	0	0	0	0
Redness-Any (n=197,199,181,180,172,172,170,169)	26.7	22.7	30	23.1
Redness-Mild (n=197,198,180,180,172,171,167,165)	24.4	21.1	28.1	21.2
Redness-Mod (n=196,197,178,175,166,169,157,163)	3.6	3.6	9.6	6.7
Redness-Sev (n=196,196,177,175,166,168,152,156)	0.6	0	0	0

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
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End point description:

Systemic events (fever [Fv] ≥ 37.5 degrees Celsius [C], fever ≥ 38 C but less than or equal to (\leq) 39 C, fever >39 C but ≤ 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
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End point timeframe:

During the 4-day period after each dose

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs were reported from baseline up to 1 month after infant series dose 3 and from toddler dose up to 1 month after toddler dose. SAE and newly diagnosed chronic medical conditions were reported from baseline up to 6 months after toddler dose

Adverse event reporting additional description:

Version was not captured, here 0.0 is mentioned for dictionary version. Local reactions and Systemic events were to be assessed only for infant series and toddler dose reporting groups.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	0.0
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Reporting groups

Reporting group title	7vPnC Infant Series
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Reporting group description:

Subjects received one single 0.5 mL dose of 7vPnC coadministered with NeisVac-C and Infanrix hexa at vaccination 1, 2. Adverse events were reported from vaccination 1 to approximately 1 month after vaccination 3.

Reporting group title	13vPnC Infant Series
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Reporting group description:

Subjects received one single 0.5 mL dose of 13vPnC coadministered with NeisVac-C and Infanrix hexa at vaccination 1, 2. Adverse events were reported from vaccination 1 to approximately 1 month after vaccination 3.

Reporting group title	13vPnC Toddler Series
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Reporting group description:

Subjects received one single 0.5 mL dose of 13vPnC coadministered with NeisVac-C and Infanrix-IPV+Hib at vaccination 4. Adverse events were reported for approximately 1 month after toddler dose.

Reporting group title	13vPnC Post-Infant Series
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Reporting group description:

Subjects received one single 0.5 mL dose of 13vPnC coadministered with Infanrix hexa at vaccination 3. Adverse events were reported from approximately 1 month after vaccination 3 to toddler dose.

Reporting group title	7vPnC Toddler Series
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Reporting group description:

Subjects received one single 0.5 mL dose of 7vPnC coadministered with NeisVac-C and Infanrix-IPV+Hib at vaccination 4. Adverse events were reported for approximately 1 month after toddler dose.

Reporting group title	7vPnC Post-Infant Series
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Reporting group description:

Subjects received one single 0.5 mL dose of 7vPnC coadministered with Infanrix hexa at vaccination 3. Adverse events were reported from approximately 1 month after vaccination 3 to toddler dose.

Reporting group title	13vPnC 6-Month Follow-up
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Reporting group description:

Subjects received one single 0.5 mL dose of 13vPnC coadministered with NeisVac-C and Infanrix hexa at vaccination 1, 2 (infant series Dose 2) and one single 0.5 mL dose of 13vPnC coadministered with Infanrix hexa at vaccination 3 (infant series dose 3). Subjects received one single 0.5 mL dose of 13vPnC coadministered with NeisVac-C and Infanrix IPV + Hib at vaccination 4 (toddler dose). MMR was administered 6 months after vaccination 4, without study vaccine. Adverse events were reported for approximately 6 months after vaccination 4.

Reporting group title	7vPnC 6-Month Follow-up
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Reporting group description:

Subjects received one single 0.5 mL dose of 7vPnC coadministered with NeisVac-C and Infanrix hexa at vaccination 1, 2 (infant series Dose 2) and one single 0.5 mL dose of 7vPnC coadministered with Infanrix hexa at vaccination 3 (infant series dose 3). Subjects received one single 0.5 mL dose of 7vPnC coadministered with NeisVac-C and Infanrix IPV + Hib at vaccination 4 (toddler dose). MMR was administered 6 months after vaccination 3, without study vaccine. Adverse events were reported for

Serious adverse events	7vPnC Infant Series	13vPnC Infant Series	13vPnC Toddler Series
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 225 (3.56%)	6 / 218 (2.75%)	1 / 209 (0.48%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Joint dislocation			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (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			
Convulsion			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	1 / 209 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (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			
Pyrexia			
subjects affected / exposed	1 / 225 (0.44%)	1 / 218 (0.46%)	1 / 209 (0.48%)
occurrences causally related to treatment / all	0 / 1	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Aphthous stomatitis			

subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (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
Coeliac disease			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (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
Diarrhoea			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (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			
subjects affected / exposed	1 / 225 (0.44%)	0 / 218 (0.00%)	0 / 209 (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			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (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
Intussusception			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Wheezing			
subjects affected / exposed	0 / 225 (0.00%)	1 / 218 (0.46%)	0 / 209 (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
Asthma			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (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
Bronchospasm			

subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (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
Increased bronchial secretion			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (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			
Bacteriuria			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	2 / 225 (0.89%)	1 / 218 (0.46%)	0 / 209 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (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
Enterocolitis viral			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (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
Escherichia urinary tract infection			
subjects affected / exposed	0 / 225 (0.00%)	1 / 218 (0.46%)	0 / 209 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 225 (0.44%)	1 / 218 (0.46%)	0 / 209 (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
Gastroenteritis rotavirus			

subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 225 (0.44%)	1 / 218 (0.46%)	0 / 209 (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
Orchitis			
subjects affected / exposed	0 / 225 (0.00%)	1 / 218 (0.46%)	0 / 209 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 225 (0.00%)	1 / 218 (0.46%)	0 / 209 (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
Pyelonephritis			
subjects affected / exposed	1 / 225 (0.44%)	0 / 218 (0.00%)	0 / 209 (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
Viral infection			
subjects affected / exposed	1 / 225 (0.44%)	0 / 218 (0.00%)	0 / 209 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			

subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (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
Pharyngotonsillitis			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (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			
Metabolic acidosis			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	13vPnC Post-Infant Series	7vPnC Toddler Series	7vPnC Post-Infant Series
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 218 (4.13%)	0 / 218 (0.00%)	6 / 225 (2.67%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Joint dislocation			
subjects affected / exposed	1 / 218 (0.46%)	0 / 218 (0.00%)	0 / 225 (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
Femur fracture			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (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			
Convulsion			

subjects affected / exposed	1 / 218 (0.46%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	1 / 218 (0.46%)	0 / 218 (0.00%)	0 / 225 (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
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 218 (0.46%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Aphthous stomatitis			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (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
Coeliac disease			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (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
Diarrhoea			
subjects affected / exposed	1 / 218 (0.46%)	0 / 218 (0.00%)	0 / 225 (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
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (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			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	1 / 225 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Intussusception			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Wheezing			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	1 / 218 (0.46%)	0 / 218 (0.00%)	0 / 225 (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
Bronchospasm			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (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
Increased bronchial secretion			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (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			
Bacteriuria			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	1 / 225 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	2 / 218 (0.92%)	0 / 218 (0.00%)	0 / 225 (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
Bronchitis			
subjects affected / exposed	1 / 218 (0.46%)	0 / 218 (0.00%)	0 / 225 (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

Enterocolitis viral			
subjects affected / exposed	1 / 218 (0.46%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (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			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	1 / 225 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	1 / 225 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 218 (0.46%)	0 / 218 (0.00%)	1 / 225 (0.44%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchitis			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 218 (0.46%)	0 / 218 (0.00%)	1 / 225 (0.44%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			

subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	1 / 218 (0.46%)	0 / 218 (0.00%)	0 / 225 (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			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (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
Pharyngotonsillitis			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (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			
Metabolic acidosis			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	13vPnC 6-Month Follow-up	7vPnC 6-Month Follow-up	
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 218 (1.83%)	9 / 224 (4.02%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Injury, poisoning and procedural complications			
Joint dislocation			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	0 / 218 (0.00%)	1 / 224 (0.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Convulsion			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile convulsion			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Aphthous stomatitis			
subjects affected / exposed	0 / 218 (0.00%)	1 / 224 (0.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coeliac disease			
subjects affected / exposed	0 / 218 (0.00%)	1 / 224 (0.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			

subjects affected / exposed	0 / 218 (0.00%)	1 / 224 (0.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroesophageal reflux disease			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intussusception			
subjects affected / exposed	0 / 218 (0.00%)	1 / 224 (0.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Wheezing			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchospasm			
subjects affected / exposed	1 / 218 (0.46%)	0 / 224 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Increased bronchial secretion			
subjects affected / exposed	0 / 218 (0.00%)	1 / 224 (0.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			

Bacteriuria			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiolitis			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis viral			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia urinary tract infection			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	0 / 218 (0.00%)	2 / 224 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	1 / 218 (0.46%)	0 / 224 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			

subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orchitis			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	2 / 218 (0.92%)	0 / 224 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	1 / 218 (0.46%)	1 / 224 (0.45%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media			
subjects affected / exposed	0 / 218 (0.00%)	1 / 224 (0.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngotonsillitis			
subjects affected / exposed	0 / 218 (0.00%)	1 / 224 (0.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis			

subjects affected / exposed	0 / 218 (0.00%)	1 / 224 (0.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Metabolic acidosis			
subjects affected / exposed	0 / 218 (0.00%)	1 / 224 (0.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	7vPnC Infant Series	13vPnC Infant Series	13vPnC Toddler Series
Total subjects affected by non-serious adverse events			
subjects affected / exposed	217 / 225 (96.44%)	211 / 218 (96.79%)	182 / 209 (87.08%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign neoplasm			
subjects affected / exposed	0 / 225 (0.00%)	1 / 218 (0.46%)	0 / 209 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	9 / 225 (4.00%)	6 / 218 (2.75%)	5 / 209 (2.39%)
occurrences (all)	9	7	5
Irritability			
subjects affected / exposed	0 / 225 (0.00%)	2 / 218 (0.92%)	0 / 209 (0.00%)
occurrences (all)	0	2	0
Developmental delay			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Fever ≥38°C but ≤39°C Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[1]	40 / 204 (19.61%)	46 / 201 (22.89%)	49 / 156 (31.41%)
occurrences (all)	40	46	49
Fever >39°C but ≤40°C Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[2] occurrences (all)	1 / 196 (0.51%) 1	2 / 196 (1.02%) 2	7 / 154 (4.55%) 7
Fever >40°C Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[3] occurrences (all)	1 / 197 (0.51%) 1	0 / 196 (0.00%) 0	1 / 152 (0.66%) 1
Decreased appetite Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[4] occurrences (all)	74 / 207 (35.75%) 74	64 / 204 (31.37%) 64	52 / 163 (31.90%) 52
Increased sleep Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[5] occurrences (all)	81 / 206 (39.32%) 81	79 / 204 (38.73%) 79	27 / 162 (16.67%) 27
Irritability Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[6] occurrences (all)	105 / 211 (49.76%) 105	94 / 202 (46.53%) 94	71 / 171 (41.52%) 71
Decreased sleep Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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: Systemic Event 0.0 alternative assessment type: Systematic			

subjects affected / exposed ^[7]	56 / 204 (27.45%)	38 / 196 (19.39%)	32 / 162 (19.75%)
occurrences (all)	56	38	32
Fever ≥38°C but ≤39°C Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[8]	79 / 189 (41.80%)	59 / 181 (32.60%)	0 / 209 (0.00%)
occurrences (all)	79	59	0
Fever >39°C but ≤40°C Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[9]	2 / 176 (1.14%)	3 / 177 (1.69%)	0 / 209 (0.00%)
occurrences (all)	2	3	0
Decreased appetite Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[10]	84 / 191 (43.98%)	88 / 189 (46.56%)	0 / 209 (0.00%)
occurrences (all)	84	88	0
Irritability Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[11]	114 / 190 (60.00%)	110 / 192 (57.29%)	0 / 209 (0.00%)
occurrences (all)	114	110	0
Increased sleep Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[12]	68 / 187 (36.36%)	74 / 189 (39.15%)	0 / 209 (0.00%)
occurrences (all)	68	74	0
Decreased sleep Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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: Systemic Event 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[13]</p> <p>occurrences (all)</p>	52 / 187 (27.81%)	50 / 183 (27.32%)	0 / 209 (0.00%)
Fever $\geq 38^{\circ}\text{C}$ but $\leq 39^{\circ}\text{C}$ Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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: Systemic Event 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[14]</p> <p>occurrences (all)</p>	51 / 176 (28.98%)	36 / 172 (20.93%)	0 / 209 (0.00%)
Fever $> 39^{\circ}\text{C}$ but $\leq 40^{\circ}\text{C}$ Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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: Systemic Event 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[15]</p> <p>occurrences (all)</p>	5 / 168 (2.98%)	6 / 166 (3.61%)	0 / 209 (0.00%)
Decreased appetite Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
<p>alternative dictionary used: Systemic Event 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[16]</p> <p>occurrences (all)</p>	64 / 178 (35.96%)	66 / 178 (37.08%)	0 / 209 (0.00%)
Increased sleep Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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: Systemic Event 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[17]</p> <p>occurrences (all)</p>	47 / 174 (27.01%)	37 / 175 (21.14%)	0 / 209 (0.00%)
Decreased sleep Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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: Systemic Event 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[18]</p> <p>occurrences (all)</p>	45 / 178 (25.28%)	40 / 175 (22.86%)	0 / 209 (0.00%)

Irritability Dose 3		Additional description: Dose 3: Subjects affected and occurrences for SE 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: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[19] occurrences (all)		74 / 188 (39.36%) 74	77 / 179 (43.02%) 77	0 / 209 (0.00%) 0
Immune system disorders				
Food allergy				
subjects affected / exposed		0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (0.00%)
occurrences (all)		0	0	0
Milk allergy				
subjects affected / exposed		1 / 225 (0.44%)	1 / 218 (0.46%)	0 / 209 (0.00%)
occurrences (all)		1	2	0
Respiratory, thoracic and mediastinal disorders				
Asthma				
subjects affected / exposed		0 / 225 (0.00%)	1 / 218 (0.46%)	0 / 209 (0.00%)
occurrences (all)		0	1	0
Infantile asthma				
subjects affected / exposed		0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (0.00%)
occurrences (all)		0	0	0
Cough				
subjects affected / exposed		2 / 225 (0.89%)	4 / 218 (1.83%)	1 / 209 (0.48%)
occurrences (all)		2	4	1
Rhinorrhoea				
subjects affected / exposed		5 / 225 (2.22%)	1 / 218 (0.46%)	0 / 209 (0.00%)
occurrences (all)		7	1	0
Wheezing				
subjects affected / exposed		3 / 225 (1.33%)	3 / 218 (1.38%)	0 / 209 (0.00%)
occurrences (all)		3	3	0
Bronchial hyperreactivity				
subjects affected / exposed		1 / 225 (0.44%)	1 / 218 (0.46%)	0 / 209 (0.00%)
occurrences (all)		1	1	0
Asphyxia				
subjects affected / exposed		0 / 225 (0.00%)	1 / 218 (0.46%)	0 / 209 (0.00%)
occurrences (all)		0	1	0
Bronchospasm				

subjects affected / exposed occurrences (all)	0 / 225 (0.00%) 0	1 / 218 (0.46%) 1	0 / 209 (0.00%) 0
Throat irritation subjects affected / exposed occurrences (all)	0 / 225 (0.00%) 0	1 / 218 (0.46%) 1	0 / 209 (0.00%) 0
Psychiatric disorders Restlessness subjects affected / exposed occurrences (all)	0 / 225 (0.00%) 0	1 / 218 (0.46%) 1	0 / 209 (0.00%) 0
Injury, poisoning and procedural complications Head injury subjects affected / exposed occurrences (all)	1 / 225 (0.44%) 1	1 / 218 (0.46%) 1	0 / 209 (0.00%) 0
Burns third degree subjects affected / exposed occurrences (all)	0 / 225 (0.00%) 0	1 / 218 (0.46%) 1	0 / 209 (0.00%) 0
Arthropod bite subjects affected / exposed occurrences (all)	0 / 225 (0.00%) 0	0 / 218 (0.00%) 0	2 / 209 (0.96%) 2
Congenital, familial and genetic disorders Thalassaemia beta subjects affected / exposed occurrences (all)	0 / 225 (0.00%) 0	0 / 218 (0.00%) 0	0 / 209 (0.00%) 0
Phimosis subjects affected / exposed occurrences (all)	0 / 225 (0.00%) 0	0 / 218 (0.00%) 0	0 / 209 (0.00%) 0
Nervous system disorders Somnolence subjects affected / exposed occurrences (all)	0 / 225 (0.00%) 0	1 / 218 (0.46%) 1	0 / 209 (0.00%) 0
Blood and lymphatic system disorders Lymphadenitis subjects affected / exposed occurrences (all)	0 / 225 (0.00%) 0	0 / 218 (0.00%) 0	0 / 209 (0.00%) 0
Ear and labyrinth disorders			

Ear pain subjects affected / exposed occurrences (all)	0 / 225 (0.00%) 0	0 / 218 (0.00%) 0	1 / 209 (0.48%) 1
Eye disorders			
Conjunctivitis subjects affected / exposed occurrences (all)	11 / 225 (4.89%) 15	3 / 218 (1.38%) 4	0 / 209 (0.00%) 0
Conjunctivitis allergic subjects affected / exposed occurrences (all)	1 / 225 (0.44%) 1	0 / 218 (0.00%) 0	0 / 209 (0.00%) 0
Dacryostenosis acquired subjects affected / exposed occurrences (all)	0 / 225 (0.00%) 0	1 / 218 (0.46%) 1	0 / 209 (0.00%) 0
Gastrointestinal disorders			
Diarrhoea subjects affected / exposed occurrences (all)	9 / 225 (4.00%) 11	8 / 218 (3.67%) 9	2 / 209 (0.96%) 2
Vomiting subjects affected / exposed occurrences (all)	4 / 225 (1.78%) 4	3 / 218 (1.38%) 4	0 / 209 (0.00%) 0
Gastrointestinal inflammation subjects affected / exposed occurrences (all)	2 / 225 (0.89%) 2	3 / 218 (1.38%) 3	0 / 209 (0.00%) 0
Constipation subjects affected / exposed occurrences (all)	2 / 225 (0.89%) 2	0 / 218 (0.00%) 0	0 / 209 (0.00%) 0
Enteritis subjects affected / exposed occurrences (all)	1 / 225 (0.44%) 1	1 / 218 (0.46%) 1	0 / 209 (0.00%) 0
Abnormal faeces subjects affected / exposed occurrences (all)	0 / 225 (0.00%) 0	1 / 218 (0.46%) 1	0 / 209 (0.00%) 0
Infantile colic subjects affected / exposed occurrences (all)	1 / 225 (0.44%) 1	0 / 218 (0.00%) 0	0 / 209 (0.00%) 0
Aphthous stomatitis			

subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	3 / 225 (1.33%)	3 / 218 (1.38%)	0 / 209 (0.00%)
occurrences (all)	5	3	0
Rash			
subjects affected / exposed	6 / 225 (2.67%)	0 / 218 (0.00%)	1 / 209 (0.48%)
occurrences (all)	6	0	1
Dermatitis			
subjects affected / exposed	0 / 225 (0.00%)	3 / 218 (1.38%)	0 / 209 (0.00%)
occurrences (all)	0	3	0
Urticaria			
subjects affected / exposed ^[20]	2 / 225 (0.89%)	1 / 218 (0.46%)	1 / 209 (0.48%)
occurrences (all)	3	1	1
Angioedema			
subjects affected / exposed	1 / 225 (0.44%)	0 / 218 (0.00%)	0 / 209 (0.00%)
occurrences (all)	1	0	0
Dermatitis diaper			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	1 / 209 (0.48%)
occurrences (all)	0	0	1
Petechiae			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	1 / 209 (0.48%)
occurrences (all)	0	0	1
Tenderness (Any) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[21]	38 / 205 (18.54%)	42 / 199 (21.11%)	47 / 164 (28.66%)
occurrences (all)	38	42	47
Tenderness (Significant) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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			

Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[22]	8 / 200 (4.00%)	6 / 199 (3.02%)	4 / 154 (2.60%)
occurrences (all)	8	6	4
Induration (Any) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[23]	29 / 200 (14.50%)	26 / 196 (13.27%)	45 / 169 (26.63%)
occurrences (all)	29	26	45
Induration (Mild) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[24]	26 / 200 (13.00%)	24 / 196 (12.24%)	38 / 166 (22.89%)
occurrences (all)	26	24	38
Induration (Moderate) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[25]	4 / 196 (2.04%)	5 / 196 (2.55%)	14 / 156 (8.97%)
occurrences (all)	4	5	14
Erythema (Any) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[26]	30 / 199 (15.08%)	30 / 197 (15.23%)	51 / 170 (30.00%)
occurrences (all)	30	30	51
Erythema (Mild) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			

subjects affected / exposed ^[27]	28 / 198 (14.14%)	29 / 197 (14.72%)	47 / 167 (28.14%)
occurrences (all)	28	29	47
Erythema (Moderate) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[28]	2 / 197 (1.02%)	1 / 196 (0.51%)	15 / 157 (9.55%)
occurrences (all)	2	1	15
Tenderness (Any) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[29]	29 / 180 (16.11%)	39 / 182 (21.43%)	0 / 209 (0.00%)
occurrences (all)	29	39	0
Tenderness (Significant) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[30]	7 / 177 (3.95%)	2 / 177 (1.13%)	0 / 209 (0.00%)
occurrences (all)	7	2	0
Induration (Any) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[31]	26 / 177 (14.69%)	40 / 182 (21.98%)	0 / 209 (0.00%)
occurrences (all)	26	40	0
Induration (Mild) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[32]	23 / 177 (12.99%)	37 / 182 (20.33%)	0 / 209 (0.00%)
occurrences (all)	23	37	0
Induration (Moderate) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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 Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[33]</p> <p>occurrences (all)</p>	4 / 175 (2.29%)	4 / 177 (2.26%)	0 / 209 (0.00%)
Erythema (Any) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
<p>alternative dictionary used: Local Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[34]</p> <p>occurrences (all)</p>	36 / 180 (20.00%)	43 / 181 (23.76%)	0 / 209 (0.00%)
Erythema (Mild) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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 Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[35]</p> <p>occurrences (all)</p>	35 / 180 (19.44%)	40 / 180 (22.22%)	0 / 209 (0.00%)
Erythema (Moderate) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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 Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[36]</p> <p>occurrences (all)</p>	2 / 175 (1.14%)	4 / 178 (2.25%)	0 / 209 (0.00%)
Tenderness (Any) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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 Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[37]</p> <p>occurrences (all)</p>	25 / 175 (14.29%)	18 / 170 (10.59%)	0 / 209 (0.00%)
Tenderness (Significant) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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 Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[38]</p> <p>occurrences (all)</p>	2 / 169 (1.18%)	2 / 167 (1.20%)	0 / 209 (0.00%)

<p>Induration (Any) Dose 3</p> <p>alternative dictionary used: Local Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[39]</p> <p>occurrences (all)</p>	Additional description: Dose 3: Subjects affected and occurrences for SE 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.		
	34 / 170 (20.00%)	40 / 171 (23.39%)	0 / 209 (0.00%)
	34	40	0
<p>Induration (Mild) Dose 3</p> <p>alternative dictionary used: Local Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[40]</p> <p>occurrences (all)</p>	Additional description: Dose 3: Subjects affected and occurrences for SE 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.		
	29 / 170 (17.06%)	35 / 171 (20.47%)	0 / 209 (0.00%)
	29	35	0
<p>Induration (Moderate) Dose 3</p> <p>alternative dictionary used: Local Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[41]</p> <p>occurrences (all)</p>	Additional description: Dose 3: Subjects affected and occurrences for SE 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.		
	10 / 168 (5.95%)	11 / 166 (6.63%)	0 / 209 (0.00%)
	10	11	0
<p>Erythema (Any) Dose 3</p> <p>alternative dictionary used: Local Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[42]</p> <p>occurrences (all)</p>	Additional description: Dose 3: Subjects affected and occurrences for SE 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.		
	39 / 172 (22.67%)	46 / 172 (26.74%)	0 / 209 (0.00%)
	39	46	0
<p>Erythema (Mild) Dose 3</p> <p>alternative dictionary used: Local Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[43]</p> <p>occurrences (all)</p>	Additional description: Dose 3: Subjects affected and occurrences for SE 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.		
	36 / 171 (21.05%)	42 / 172 (24.42%)	0 / 209 (0.00%)
	36	42	0
<p>Erythema (Moderate) Dose 3</p> <p>alternative dictionary used: Local Reaction 0.0</p> <p>alternative assessment type: Systematic</p>	Additional description: Dose 3: Subjects affected and occurrences for SE 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 ^[44]	6 / 169 (3.55%)	6 / 166 (3.61%)	0 / 209 (0.00%)
occurrences (all)	6	6	0
Erythema (Severe) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[45]	0 / 168 (0.00%)	1 / 166 (0.60%)	0 / 209 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Herpangina			
subjects affected / exposed	0 / 225 (0.00%)	1 / 218 (0.46%)	0 / 209 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	27 / 225 (12.00%)	21 / 218 (9.63%)	9 / 209 (4.31%)
occurrences (all)	31	27	10
Upper respiratory tract infection			
subjects affected / exposed	24 / 225 (10.67%)	23 / 218 (10.55%)	5 / 209 (2.39%)
occurrences (all)	36	34	5
Gastroenteritis			
subjects affected / exposed	15 / 225 (6.67%)	19 / 218 (8.72%)	7 / 209 (3.35%)
occurrences (all)	16	19	7
Bronchiolitis			
subjects affected / exposed	17 / 225 (7.56%)	12 / 218 (5.50%)	1 / 209 (0.48%)
occurrences (all)	20	15	1
Respiratory tract infection			
subjects affected / exposed	14 / 225 (6.22%)	9 / 218 (4.13%)	0 / 209 (0.00%)
occurrences (all)	17	11	0
Bronchitis			
subjects affected / exposed	13 / 225 (5.78%)	9 / 218 (4.13%)	1 / 209 (0.48%)
occurrences (all)	15	9	1
Laryngitis			
subjects affected / exposed	8 / 225 (3.56%)	5 / 218 (2.29%)	1 / 209 (0.48%)
occurrences (all)	8	5	1
Otitis media			

subjects affected / exposed	8 / 225 (3.56%)	3 / 218 (1.38%)	0 / 209 (0.00%)
occurrences (all)	8	6	0
Rhinitis			
subjects affected / exposed	7 / 225 (3.11%)	4 / 218 (1.83%)	0 / 209 (0.00%)
occurrences (all)	7	5	0
Ear infection			
subjects affected / exposed	5 / 225 (2.22%)	5 / 218 (2.29%)	0 / 209 (0.00%)
occurrences (all)	5	6	0
Pharyngitis			
subjects affected / exposed	2 / 225 (0.89%)	4 / 218 (1.83%)	5 / 209 (2.39%)
occurrences (all)	2	4	5
Tonsillitis			
subjects affected / exposed	3 / 225 (1.33%)	2 / 218 (0.92%)	1 / 209 (0.48%)
occurrences (all)	4	2	1
Viral infection			
subjects affected / exposed	4 / 225 (1.78%)	1 / 218 (0.46%)	2 / 209 (0.96%)
occurrences (all)	4	1	2
Candidiasis			
subjects affected / exposed	3 / 225 (1.33%)	1 / 218 (0.46%)	0 / 209 (0.00%)
occurrences (all)	3	1	0
Otitis media acute			
subjects affected / exposed	2 / 225 (0.89%)	1 / 218 (0.46%)	2 / 209 (0.96%)
occurrences (all)	2	1	2
Varicella			
subjects affected / exposed	2 / 225 (0.89%)	1 / 218 (0.46%)	0 / 209 (0.00%)
occurrences (all)	2	1	0
Oral candidiasis			
subjects affected / exposed	1 / 225 (0.44%)	1 / 218 (0.46%)	0 / 209 (0.00%)
occurrences (all)	1	1	0
Urinary tract infection			
subjects affected / exposed	0 / 225 (0.00%)	2 / 218 (0.92%)	1 / 209 (0.48%)
occurrences (all)	0	2	1
Acarodermatitis			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Injection site abscess			

subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	1 / 209 (0.48%)
occurrences (all)	0	0	1
Fungal skin infection			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection			
subjects affected / exposed	1 / 225 (0.44%)	0 / 218 (0.00%)	0 / 209 (0.00%)
occurrences (all)	1	0	0
Lice infestation			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	1 / 209 (0.48%)
occurrences (all)	0	0	1
Pharyngotonsillitis			
subjects affected / exposed	1 / 225 (0.44%)	0 / 218 (0.00%)	1 / 209 (0.48%)
occurrences (all)	1	0	1
Pneumonia			
subjects affected / exposed	0 / 225 (0.00%)	1 / 218 (0.46%)	0 / 209 (0.00%)
occurrences (all)	0	1	0
Roseola			
subjects affected / exposed	0 / 225 (0.00%)	1 / 218 (0.46%)	0 / 209 (0.00%)
occurrences (all)	0	1	0
Viral rash			
subjects affected / exposed	0 / 225 (0.00%)	0 / 218 (0.00%)	1 / 209 (0.48%)
occurrences (all)	0	0	1
Bronchopneumonia			
subjects affected / exposed	0 / 225 (0.00%)	1 / 218 (0.46%)	0 / 209 (0.00%)
occurrences (all)	0	1	0
Campylobacter gastroenteritis			
subjects affected / exposed	1 / 225 (0.44%)	0 / 218 (0.00%)	0 / 209 (0.00%)
occurrences (all)	1	0	0
Campylobacter intestinal infection			
subjects affected / exposed	0 / 225 (0.00%)	1 / 218 (0.46%)	0 / 209 (0.00%)
occurrences (all)	0	1	0
Croup infectious			

subjects affected / exposed	0 / 225 (0.00%)	1 / 218 (0.46%)	0 / 209 (0.00%)
occurrences (all)	0	1	0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 225 (0.00%)	1 / 218 (0.46%)	0 / 209 (0.00%)
occurrences (all)	0	2	0
Exanthema subitum			
subjects affected / exposed	0 / 225 (0.00%)	1 / 218 (0.46%)	0 / 209 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis rotavirus			
subjects affected / exposed	1 / 225 (0.44%)	0 / 218 (0.00%)	0 / 209 (0.00%)
occurrences (all)	1	0	0
Paronychia			
subjects affected / exposed	1 / 225 (0.44%)	0 / 218 (0.00%)	0 / 209 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 225 (0.00%)	1 / 218 (0.46%)	0 / 209 (0.00%)
occurrences (all)	0	2	0
Viral skin infection			
subjects affected / exposed	1 / 225 (0.44%)	0 / 218 (0.00%)	0 / 209 (0.00%)
occurrences (all)	1	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 225 (0.00%)	1 / 218 (0.46%)	0 / 209 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Cow's milk intolerance			
subjects affected / exposed	1 / 225 (0.44%)	1 / 218 (0.46%)	0 / 209 (0.00%)
occurrences (all)	1	1	0
Anorexia			
subjects affected / exposed	0 / 225 (0.00%)	1 / 218 (0.46%)	1 / 209 (0.48%)
occurrences (all)	0	2	1
Failure to thrive			
subjects affected / exposed	0 / 225 (0.00%)	1 / 218 (0.46%)	0 / 209 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	13vPnC Post-Infant Series	7vPnC Toddler Series	7vPnC Post-Infant Series
Total subjects affected by non-serious adverse events			

subjects affected / exposed	6 / 218 (2.75%)	193 / 218 (88.53%)	13 / 225 (5.78%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign neoplasm			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 218 (0.00%)	2 / 218 (0.92%)	0 / 225 (0.00%)
occurrences (all)	0	2	0
Irritability			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Developmental delay			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	1 / 225 (0.44%)
occurrences (all)	0	0	1
Fever $\geq 38^{\circ}\text{C}$ but $\leq 39^{\circ}\text{C}$ Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[1]	0 / 218 (0.00%)	58 / 169 (34.32%)	0 / 225 (0.00%)
occurrences (all)	0	58	0
Fever $> 39^{\circ}\text{C}$ but $\leq 40^{\circ}\text{C}$ Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[2]	0 / 218 (0.00%)	4 / 156 (2.56%)	0 / 225 (0.00%)
occurrences (all)	0	4	0
Fever $> 40^{\circ}\text{C}$ Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[3]	0 / 218 (0.00%)	0 / 156 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Decreased appetite Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used:			

Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[4]	0 / 218 (0.00%)	73 / 178 (41.01%)	0 / 225 (0.00%)
occurrences (all)	0	73	0
Increased sleep Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[5]	0 / 218 (0.00%)	41 / 165 (24.85%)	0 / 225 (0.00%)
occurrences (all)	0	41	0
Irritability Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[6]	0 / 218 (0.00%)	96 / 179 (53.63%)	0 / 225 (0.00%)
occurrences (all)	0	96	0
Decreased sleep Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[7]	0 / 218 (0.00%)	31 / 166 (18.67%)	0 / 225 (0.00%)
occurrences (all)	0	31	0
Fever ≥38°C but ≤39°C Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[8]	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Fever >39°C but ≤40°C Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[9]	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0

Decreased appetite Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[10]	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Irritability Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[11]	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Increased sleep Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[12]	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Decreased sleep Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[13]	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Fever ≥38°C but ≤39°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[14]	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Fever >39°C but ≤40°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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: Systemic Event 0.0			
alternative assessment type: Systematic			

subjects affected / exposed ^[15] occurrences (all)	0 / 218 (0.00%) 0	0 / 218 (0.00%) 0	0 / 225 (0.00%) 0
Decreased appetite Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[16] occurrences (all)	0 / 218 (0.00%) 0	0 / 218 (0.00%) 0	0 / 225 (0.00%) 0
Increased sleep Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[17] occurrences (all)	0 / 218 (0.00%) 0	0 / 218 (0.00%) 0	0 / 225 (0.00%) 0
Decreased sleep Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[18] occurrences (all)	0 / 218 (0.00%) 0	0 / 218 (0.00%) 0	0 / 225 (0.00%) 0
Irritability Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[19] occurrences (all)	0 / 218 (0.00%) 0	0 / 218 (0.00%) 0	0 / 225 (0.00%) 0
Immune system disorders			
Food allergy subjects affected / exposed occurrences (all)	1 / 218 (0.46%) 1	0 / 218 (0.00%) 0	0 / 225 (0.00%) 0
Milk allergy subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 218 (0.00%) 0	1 / 225 (0.44%) 1
Respiratory, thoracic and mediastinal disorders			

Asthma			
subjects affected / exposed	1 / 218 (0.46%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	2	0	0
Infantile asthma			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	1 / 218 (0.46%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	1	0	0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Asphyxia			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Bronchospasm			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Restlessness			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	0 / 218 (0.00%)	1 / 218 (0.46%)	0 / 225 (0.00%)
occurrences (all)	0	1	0
Burns third degree			

subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 218 (0.00%) 0	0 / 225 (0.00%) 0
Arthropod bite subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 218 (0.00%) 0	0 / 225 (0.00%) 0
Congenital, familial and genetic disorders Thalassaemia beta subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 218 (0.00%) 0	0 / 225 (0.00%) 0
Phimosi subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 218 (0.00%) 0	1 / 225 (0.44%) 1
Nervous system disorders Somnolence subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 218 (0.00%) 0	0 / 225 (0.00%) 0
Blood and lymphatic system disorders Lymphadenitis subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	1 / 218 (0.46%) 1	0 / 225 (0.00%) 0
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 218 (0.00%) 0	0 / 225 (0.00%) 0
Eye disorders Conjunctivitis subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	1 / 218 (0.46%) 1	0 / 225 (0.00%) 0
Conjunctivitis allergic subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 218 (0.00%) 0	0 / 225 (0.00%) 0
Dacryostenosis acquired subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 218 (0.00%) 0	0 / 225 (0.00%) 0
Gastrointestinal disorders			

Diarrhoea			
subjects affected / exposed	0 / 218 (0.00%)	3 / 218 (1.38%)	1 / 225 (0.44%)
occurrences (all)	0	3	1
Vomiting			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal inflammation			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Abnormal faeces			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Infantile colic			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Aphthous stomatitis			
subjects affected / exposed	0 / 218 (0.00%)	1 / 218 (0.46%)	0 / 225 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	0 / 218 (0.00%)	1 / 218 (0.46%)	0 / 225 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	1 / 218 (0.46%)	0 / 218 (0.00%)	2 / 225 (0.89%)
occurrences (all)	1	0	2
Rash			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Dermatitis			

subjects affected / exposed	0 / 218 (0.00%)	1 / 218 (0.46%)	0 / 225 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed ^[20]	0 / 218 (0.00%)	1 / 218 (0.46%)	0 / 225 (0.00%)
occurrences (all)	0	1	0
Angioedema			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Tenderness (Any) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[21]	0 / 218 (0.00%)	46 / 172 (26.74%)	0 / 225 (0.00%)
occurrences (all)	0	46	0
Tenderness (Significant) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[22]	0 / 218 (0.00%)	6 / 160 (3.75%)	0 / 225 (0.00%)
occurrences (all)	0	6	0
Induration (Any) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[23]	0 / 218 (0.00%)	31 / 168 (18.45%)	0 / 225 (0.00%)
occurrences (all)	0	31	0
Induration (Mild) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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			

Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[24]	0 / 218 (0.00%)	26 / 163 (15.95%)	0 / 225 (0.00%)
occurrences (all)	0	26	0
Induration (Moderate) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[25]	0 / 218 (0.00%)	9 / 163 (5.52%)	0 / 225 (0.00%)
occurrences (all)	0	9	0
Erythema (Any) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[26]	0 / 218 (0.00%)	39 / 169 (23.08%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Erythema (Mild) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[27]	0 / 218 (0.00%)	35 / 165 (21.21%)	0 / 225 (0.00%)
occurrences (all)	0	35	0
Erythema (Moderate) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[28]	0 / 218 (0.00%)	11 / 163 (6.75%)	0 / 225 (0.00%)
occurrences (all)	0	11	0
Tenderness (Any) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[29]	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0

Tenderness (Significant) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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 Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed ^[30] occurrences (all)	0 / 218 (0.00%) 0	0 / 218 (0.00%) 0	0 / 225 (0.00%) 0
Induration (Any) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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 Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed ^[31] occurrences (all)	0 / 218 (0.00%) 0	0 / 218 (0.00%) 0	0 / 225 (0.00%) 0
Induration (Mild) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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 Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed ^[32] occurrences (all)	0 / 218 (0.00%) 0	0 / 218 (0.00%) 0	0 / 225 (0.00%) 0
Induration (Moderate) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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 Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed ^[33] occurrences (all)	0 / 218 (0.00%) 0	0 / 218 (0.00%) 0	0 / 225 (0.00%) 0
Erythema (Any) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed ^[34] occurrences (all)	0 / 218 (0.00%) 0	0 / 218 (0.00%) 0	0 / 225 (0.00%) 0
Erythema (Mild) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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 Reaction 0.0 alternative assessment type: Systematic			

subjects affected / exposed ^[35]	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Erythema (Moderate) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[36]	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Tenderness (Any) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[37]	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Tenderness (Significant) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[38]	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Induration (Any) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[39]	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Induration (Mild) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[40]	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Induration (Moderate) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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 Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[41]</p> <p>occurrences (all)</p>	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
Erythema (Any) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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 Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[42]</p> <p>occurrences (all)</p>	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
Erythema (Mild) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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 Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[43]</p> <p>occurrences (all)</p>	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
Erythema (Moderate) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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 Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[44]</p> <p>occurrences (all)</p>	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
Erythema (Severe) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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 Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[45]</p> <p>occurrences (all)</p>	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
Infections and infestations			
Herpangina			
<p>subjects affected / exposed</p> <p>occurrences (all)</p>	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
Nasopharyngitis			

subjects affected / exposed	0 / 218 (0.00%)	6 / 218 (2.75%)	1 / 225 (0.44%)
occurrences (all)	0	6	1
Upper respiratory tract infection			
subjects affected / exposed	1 / 218 (0.46%)	4 / 218 (1.83%)	2 / 225 (0.89%)
occurrences (all)	1	4	2
Gastroenteritis			
subjects affected / exposed	0 / 218 (0.00%)	3 / 218 (1.38%)	0 / 225 (0.00%)
occurrences (all)	0	3	0
Bronchiolitis			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 218 (0.00%)	1 / 218 (0.46%)	0 / 225 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
subjects affected / exposed	0 / 218 (0.00%)	1 / 218 (0.46%)	1 / 225 (0.44%)
occurrences (all)	0	1	1
Laryngitis			
subjects affected / exposed	0 / 218 (0.00%)	1 / 218 (0.46%)	0 / 225 (0.00%)
occurrences (all)	0	1	0
Otitis media			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 218 (0.00%)	5 / 218 (2.29%)	1 / 225 (0.44%)
occurrences (all)	0	5	1
Pharyngitis			
subjects affected / exposed	0 / 218 (0.00%)	3 / 218 (1.38%)	0 / 225 (0.00%)
occurrences (all)	0	3	0
Tonsillitis			
subjects affected / exposed	0 / 218 (0.00%)	4 / 218 (1.83%)	0 / 225 (0.00%)
occurrences (all)	0	5	0
Viral infection			

subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Candidiasis			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Varicella			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	1 / 225 (0.44%)
occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 218 (0.00%)	1 / 218 (0.46%)	0 / 225 (0.00%)
occurrences (all)	0	1	0
Acarodermatitis			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	1 / 225 (0.44%)
occurrences (all)	0	0	1
Injection site abscess			
subjects affected / exposed	1 / 218 (0.46%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	1	0	0
Oral herpes			
subjects affected / exposed	0 / 218 (0.00%)	1 / 218 (0.46%)	0 / 225 (0.00%)
occurrences (all)	0	1	0
Fungal skin infection			
subjects affected / exposed	0 / 218 (0.00%)	1 / 218 (0.46%)	0 / 225 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal infection			
subjects affected / exposed	0 / 218 (0.00%)	1 / 218 (0.46%)	0 / 225 (0.00%)
occurrences (all)	0	1	0
Lice infestation			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Pharyngotonsillitis			

subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 218 (0.00%)	1 / 218 (0.46%)	0 / 225 (0.00%)
occurrences (all)	0	1	0
Roseola			
subjects affected / exposed	0 / 218 (0.00%)	1 / 218 (0.46%)	0 / 225 (0.00%)
occurrences (all)	0	1	0
Viral rash			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Bronchopneumonia			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Campylobacter intestinal infection			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Croup infectious			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Exanthema subitum			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 218 (0.00%)	0 / 218 (0.00%)	0 / 225 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			

subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 218 (0.00%) 0	0 / 225 (0.00%) 0
Viral skin infection subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 218 (0.00%) 0	0 / 225 (0.00%) 0
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 218 (0.00%) 0	0 / 225 (0.00%) 0
Metabolism and nutrition disorders Cow's milk intolerance subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 218 (0.00%) 0	1 / 225 (0.44%) 1
Anorexia subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 218 (0.00%) 0	0 / 225 (0.00%) 0
Failure to thrive subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 218 (0.00%) 0	0 / 225 (0.00%) 0

Non-serious adverse events	13vPnC 6-Month Follow-up	7vPnC 6-Month Follow-up	
Total subjects affected by non-serious adverse events subjects affected / exposed	4 / 218 (1.83%)	2 / 224 (0.89%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Benign neoplasm subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
General disorders and administration site conditions Pyrexia subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Irritability subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Developmental delay subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	

<div>Fever $\geq 38^{\circ}\text{C}$ but $\leq 39^{\circ}\text{C}$ Dose 1</div> <div><div>alternative dictionary used: Systemic Event 0.0</div><div>alternative assessment type: Systematic</div><div>subjects affected / exposed^[1]</div><div>occurrences (all)</div></div>	<div>Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</div> <table><tr><td>0 / 218 (0.00%)</td><td>0 / 224 (0.00%)</td><td></td></tr><tr><td>0</td><td>0</td><td></td></tr></table>			0 / 218 (0.00%)	0 / 224 (0.00%)		0	0	
0 / 218 (0.00%)	0 / 224 (0.00%)								
0	0								
<div>Fever $> 39^{\circ}\text{C}$ but $\leq 40^{\circ}\text{C}$ Dose 1</div> <div><div>alternative dictionary used: Systemic Event 0.0</div><div>alternative assessment type: Systematic</div><div>subjects affected / exposed^[2]</div><div>occurrences (all)</div></div>	<div>Additional description: Dose 1: Subjects affected and occurrences for SE 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.</div> <table><tr><td>0 / 218 (0.00%)</td><td>0 / 224 (0.00%)</td><td></td></tr><tr><td>0</td><td>0</td><td></td></tr></table>			0 / 218 (0.00%)	0 / 224 (0.00%)		0	0	
0 / 218 (0.00%)	0 / 224 (0.00%)								
0	0								
<div>Fever $> 40^{\circ}\text{C}$ Dose 1</div> <div><div>alternative dictionary used: Systemic Event 0.0</div><div>alternative assessment type: Systematic</div><div>subjects affected / exposed^[3]</div><div>occurrences (all)</div></div>	<div>Additional description: Dose 1: Subjects affected and occurrences for SE 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.</div> <table><tr><td>0 / 218 (0.00%)</td><td>0 / 224 (0.00%)</td><td></td></tr><tr><td>0</td><td>0</td><td></td></tr></table>			0 / 218 (0.00%)	0 / 224 (0.00%)		0	0	
0 / 218 (0.00%)	0 / 224 (0.00%)								
0	0								
<div>Decreased appetite Dose 1</div> <div><div>alternative dictionary used: Systemic Event 0.0</div><div>alternative assessment type: Systematic</div><div>subjects affected / exposed^[4]</div><div>occurrences (all)</div></div>	<div>Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</div> <table><tr><td>0 / 218 (0.00%)</td><td>0 / 224 (0.00%)</td><td></td></tr><tr><td>0</td><td>0</td><td></td></tr></table>			0 / 218 (0.00%)	0 / 224 (0.00%)		0	0	
0 / 218 (0.00%)	0 / 224 (0.00%)								
0	0								
<div>Increased sleep Dose 1</div> <div><div>alternative dictionary used: Systemic Event 0.0</div><div>alternative assessment type: Systematic</div><div>subjects affected / exposed^[5]</div><div>occurrences (all)</div></div>	<div>Additional description: Dose 1: Subjects affected and occurrences for SE 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.</div> <table><tr><td>0 / 218 (0.00%)</td><td>0 / 224 (0.00%)</td><td></td></tr><tr><td>0</td><td>0</td><td></td></tr></table>			0 / 218 (0.00%)	0 / 224 (0.00%)		0	0	
0 / 218 (0.00%)	0 / 224 (0.00%)								
0	0								
<div>Irritability Dose 1</div> <div><div>alternative dictionary used: Systemic Event 0.0</div><div>alternative assessment type: Systematic</div></div>	<div>Additional description: Dose 1: Subjects affected and occurrences for SE 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.</div> <table><tr><td></td><td></td><td></td></tr></table>								

subjects affected / exposed ^[6] occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Decreased sleep Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[7] occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Fever ≥38°C but ≤39°C Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[8] occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Fever >39°C but ≤40°C Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[9] occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Decreased appetite Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[10] occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Irritability Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[11] occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Increased sleep Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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: Systemic Event 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[12]</p> <p>occurrences (all)</p>	0 / 218 (0.00%)	0 / 224 (0.00%)	
Decreased sleep Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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: Systemic Event 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[13]</p> <p>occurrences (all)</p>	0 / 218 (0.00%)	0 / 224 (0.00%)	
Fever ≥38°C but ≤39°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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: Systemic Event 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[14]</p> <p>occurrences (all)</p>	0 / 218 (0.00%)	0 / 224 (0.00%)	
Fever >39°C but ≤40°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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: Systemic Event 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[15]</p> <p>occurrences (all)</p>	0 / 218 (0.00%)	0 / 224 (0.00%)	
Decreased appetite Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
<p>alternative dictionary used: Systemic Event 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[16]</p> <p>occurrences (all)</p>	0 / 218 (0.00%)	0 / 224 (0.00%)	
Increased sleep Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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: Systemic Event 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[17]</p> <p>occurrences (all)</p>	0 / 218 (0.00%)	0 / 224 (0.00%)	

<p>Decreased sleep Dose 3</p> <p>alternative dictionary used: Systemic Event 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[18]</p> <p>occurrences (all)</p>	Additional description: Dose 3: Subjects affected and occurrences for SE 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 / 218 (0.00%)	0 / 224 (0.00%)	
	0	0	
<p>Irritability Dose 3</p> <p>alternative dictionary used: Systemic Event 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[19]</p> <p>occurrences (all)</p>	Additional description: Dose 3: Subjects affected and occurrences for SE 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 / 218 (0.00%)	0 / 224 (0.00%)	
	0	0	
<p>Immune system disorders</p> <p>Food allergy</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Milk allergy</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	1 / 218 (0.46%)	1 / 224 (0.45%)	
	1	1	
	0 / 218 (0.00%)	0 / 224 (0.00%)	
	0	0	
<p>Respiratory, thoracic and mediastinal disorders</p> <p>Asthma</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Infantile asthma</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Cough</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Rhinorrhoea</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Wheezing</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	0 / 218 (0.00%)	1 / 224 (0.45%)	
	0	1	
	1 / 218 (0.46%)	0 / 224 (0.00%)	
	1	0	
	0 / 218 (0.00%)	0 / 224 (0.00%)	
	0	0	
	0 / 218 (0.00%)	0 / 224 (0.00%)	
	0	0	
	0 / 218 (0.00%)	0 / 224 (0.00%)	
	0	0	
	0 / 218 (0.00%)	0 / 224 (0.00%)	
	0	0	

Bronchial hyperreactivity subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Asphyxia subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Bronchospasm subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Throat irritation subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Psychiatric disorders Restlessness subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Injury, poisoning and procedural complications Head injury subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Burns third degree subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Arthropod bite subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Congenital, familial and genetic disorders Thalassaemia beta subjects affected / exposed occurrences (all)	1 / 218 (0.46%) 1	0 / 224 (0.00%) 0	
Phimosis subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Nervous system disorders Somnolence			

subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Blood and lymphatic system disorders Lymphadenitis subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Eye disorders Conjunctivitis subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Conjunctivitis allergic subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Dacryostenosis acquired subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Vomiting subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Gastrointestinal inflammation subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Constipation subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Enteritis subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Abnormal faeces			

subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Infantile colic subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Aphthous stomatitis subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Stomatitis subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Skin and subcutaneous tissue disorders			
Dermatitis atopic subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Rash subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Dermatitis subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Urticaria subjects affected / exposed ^[20] occurrences (all)	0 / 209 (0.00%) 0	0 / 224 (0.00%) 0	
Angioedema subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Dermatitis diaper subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Petechiae subjects affected / exposed occurrences (all)	0 / 218 (0.00%) 0	0 / 224 (0.00%) 0	
Tenderness (Any) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries 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 Reaction 0.0			

<p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[21]</p> <p>occurrences (all)</p>	<p>0 / 218 (0.00%)</p> <p>0</p>	<p>0 / 224 (0.00%)</p> <p>0</p>	
Tenderness (Significant) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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 Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[22]</p> <p>occurrences (all)</p>	<p>0 / 218 (0.00%)</p> <p>0</p>	<p>0 / 224 (0.00%)</p> <p>0</p>	
Induration (Any) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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 Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[23]</p> <p>occurrences (all)</p>	<p>0 / 218 (0.00%)</p> <p>0</p>	<p>0 / 224 (0.00%)</p> <p>0</p>	
Induration (Mild) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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 Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[24]</p> <p>occurrences (all)</p>	<p>0 / 218 (0.00%)</p> <p>0</p>	<p>0 / 224 (0.00%)</p> <p>0</p>	
Induration (Moderate) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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 Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[25]</p> <p>occurrences (all)</p>	<p>0 / 218 (0.00%)</p> <p>0</p>	<p>0 / 224 (0.00%)</p> <p>0</p>	
Erythema (Any) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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 Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[26]</p> <p>occurrences (all)</p>	<p>0 / 218 (0.00%)</p> <p>0</p>	<p>0 / 224 (0.00%)</p> <p>0</p>	
Erythema (Mild) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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 Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[27]</p> <p>occurrences (all)</p>	0 / 218 (0.00%)	0 / 224 (0.00%)
	0	0
Erythema (Moderate) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE 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 Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[28]</p> <p>occurrences (all)</p>	0 / 218 (0.00%)	0 / 224 (0.00%)
	0	0
Tenderness (Any) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.	
<p>alternative dictionary used: Local Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[29]</p> <p>occurrences (all)</p>	0 / 218 (0.00%)	0 / 224 (0.00%)
	0	0
Tenderness (Significant) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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 Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[30]</p> <p>occurrences (all)</p>	0 / 218 (0.00%)	0 / 224 (0.00%)
	0	0
Induration (Any) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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 Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[31]</p> <p>occurrences (all)</p>	0 / 218 (0.00%)	0 / 224 (0.00%)
	0	0
Induration (Mild) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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 Reaction 0.0</p> <p>alternative assessment type: Systematic</p>		

subjects affected / exposed ^[32]	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences (all)	0	0	
Induration (Moderate) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[33]	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences (all)	0	0	
Erythema (Any) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[34]	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences (all)	0	0	
Erythema (Mild) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[35]	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences (all)	0	0	
Erythema (Moderate) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[36]	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences (all)	0	0	
Tenderness (Any) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[37]	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences (all)	0	0	
Tenderness (Significant) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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 Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[38]</p> <p>occurrences (all)</p>	0 / 218 (0.00%)	0 / 224 (0.00%)	
Induration (Any) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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 Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[39]</p> <p>occurrences (all)</p>	0 / 218 (0.00%)	0 / 224 (0.00%)	
Induration (Mild) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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 Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[40]</p> <p>occurrences (all)</p>	0 / 218 (0.00%)	0 / 224 (0.00%)	
Induration (Moderate) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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 Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[41]</p> <p>occurrences (all)</p>	0 / 218 (0.00%)	0 / 224 (0.00%)	
Erythema (Any) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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 Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[42]</p> <p>occurrences (all)</p>	0 / 218 (0.00%)	0 / 224 (0.00%)	
Erythema (Mild) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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 Reaction 0.0</p> <p>alternative assessment type: Systematic</p>			

subjects affected / exposed ^[43]	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences (all)	0	0	
Erythema (Moderate) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[44]	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences (all)	0	0	
Erythema (Severe) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[45]	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Herpangina			
subjects affected / exposed	1 / 218 (0.46%)	0 / 224 (0.00%)	
occurrences (all)	1	0	
Nasopharyngitis			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences (all)	0	0	
Bronchiolitis			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences (all)	0	0	
Respiratory tract infection			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences (all)	0	0	
Bronchitis			

subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0
Laryngitis		
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0
Otitis media		
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0
Rhinitis		
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0
Ear infection		
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0
Pharyngitis		
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0
Tonsillitis		
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0
Viral infection		
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0
Candidiasis		
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0
Otitis media acute		
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0
Varicella		
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0
Oral candidiasis		
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0
Urinary tract infection		

subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0
Acarodermatitis		
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0
Injection site abscess		
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0
Oral herpes		
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0
Fungal skin infection		
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0
Gastrointestinal infection		
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0
Lice infestation		
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0
Pharyngotonsillitis		
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0
Pneumonia		
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0
Roseola		
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0
Viral rash		
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0
Bronchopneumonia		
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0
Campylobacter gastroenteritis		

subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences (all)	0	0	
Campylobacter intestinal infection			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences (all)	0	0	
Croup infectious			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences (all)	0	0	
Escherichia urinary tract infection			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences (all)	0	0	
Exanthema subitum			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences (all)	0	0	
Paronychia			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences (all)	0	0	
Respiratory tract infection viral			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences (all)	0	0	
Viral skin infection			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences (all)	0	0	
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Cow's milk intolerance			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences (all)	0	0	
Anorexia			
subjects affected / exposed	0 / 218 (0.00%)	0 / 224 (0.00%)	
occurrences (all)	0	0	

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
01 May 2007	Previous vaccination with meningococcal vaccine and contraindication to vaccination with meningococcal vaccine was added as exclusion criteria.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported