



Clinical trial results:

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

Summary

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

Results information

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

Trial information

Trial identification

Sponsor protocol code	6096A1-3006
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Additional study identifiers

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

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

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

Notes:

General information about the trial

Main objective of the trial:

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

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

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

Notes:

Population of trial subjects

Subjects enrolled per country

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

Notes:

Subjects enrolled per age group

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

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

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

Period 1

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

Arms

Are arms mutually exclusive?	Yes
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Arm title	13vPnC Infant series
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Arm description:

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

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

Dosage and administration details:

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

Arm title	7vPnC Infant series
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Arm description:

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

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

Dosage and administration details:

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

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

Period 2

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

Arms

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

Arm description:

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

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

Arm title	7vPnC After Infant series
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Arm description:

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

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

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

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

Period 3

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

Arms

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

Arm description:

13vPnC administered at 12 months of age.

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

Dosage and administration details:

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

Arm title	7vPnC Toddler dose
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Arm description:

7vPnC administered at 12 months of age.

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

Dosage and administration details:

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

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

Baseline characteristics

Reporting groups

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

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

Subject analysis sets

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

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

Male			
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End points

End points reporting groups

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

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

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

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

Statistical analyses

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

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

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

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

End point type	Secondary
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End point timeframe:

Month 7, 12, 13, 18, 24

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

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

Statistical analyses

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

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

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

independent variable.

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

Statistical analysis title

Month 18

Statistical analysis description:

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

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

Statistical analysis title

Month 24

Statistical analysis description:

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

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

Adverse events

Adverse events information

Timeframe for reporting adverse events:

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

Adverse event reporting additional description:

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

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	14.0

Reporting groups

Reporting group title	Infant Series 13vPnC
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Reporting group description:

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

Reporting group title	Infant Series 7vPnC
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Reporting group description:

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

Reporting group title	After Infant Series 13vPnC
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Reporting group description:

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

Reporting group title	After Infant Series 7vPnC
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Reporting group description:

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

Reporting group title	Toddler Dose 13vPnC
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Reporting group description:

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

Reporting group title	Toddler Dose 7vPnC
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Reporting group description:

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

Reporting group title	After Toddler Dose 13vPnC
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Reporting group description:

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

Reporting group title	After Toddler Dose 7vPnC
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Reporting group description:

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

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

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

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

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

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

subjects affected / exposed	0 / 930 (0.00%)	0 / 933 (0.00%)	0 / 929 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fractured base			
subjects affected / exposed	0 / 930 (0.00%)	0 / 933 (0.00%)	0 / 929 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laceration			
subjects affected / exposed	0 / 930 (0.00%)	0 / 933 (0.00%)	0 / 929 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental poisoning			
subjects affected / exposed	0 / 930 (0.00%)	0 / 933 (0.00%)	0 / 929 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	0 / 930 (0.00%)	0 / 933 (0.00%)	0 / 929 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 930 (0.00%)	0 / 933 (0.00%)	0 / 929 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	0 / 930 (0.00%)	0 / 933 (0.00%)	0 / 929 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mouth injury			
subjects affected / exposed	0 / 930 (0.00%)	0 / 933 (0.00%)	0 / 929 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative fever			

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

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

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

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

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

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

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

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

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

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

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

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

subjects affected / exposed	2 / 930 (0.22%)	0 / 933 (0.00%)	0 / 929 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 930 (0.00%)	1 / 933 (0.11%)	0 / 929 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight gain poor			
subjects affected / exposed	0 / 930 (0.00%)	1 / 933 (0.11%)	0 / 929 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeding disorder			
subjects affected / exposed	0 / 930 (0.00%)	0 / 933 (0.00%)	1 / 929 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

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

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

subjects affected / exposed	0 / 931 (0.00%)	0 / 882 (0.00%)	0 / 875 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	2 / 931 (0.21%)	1 / 882 (0.11%)	2 / 875 (0.23%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep apnoea syndrome			
subjects affected / exposed	1 / 931 (0.11%)	0 / 882 (0.00%)	1 / 875 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	0 / 931 (0.00%)	1 / 882 (0.11%)	0 / 875 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	2 / 931 (0.21%)	0 / 882 (0.00%)	0 / 875 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 931 (0.00%)	0 / 882 (0.00%)	0 / 875 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 931 (0.00%)	0 / 882 (0.00%)	0 / 875 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Breath holding			
subjects affected / exposed	0 / 931 (0.00%)	0 / 882 (0.00%)	0 / 875 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Restlessness			

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

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

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

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

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

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

subjects affected / exposed	0 / 931 (0.00%)	0 / 882 (0.00%)	0 / 875 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 931 (0.00%)	0 / 882 (0.00%)	0 / 875 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatomegaly			
subjects affected / exposed	0 / 931 (0.00%)	0 / 882 (0.00%)	1 / 875 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 931 (0.00%)	0 / 882 (0.00%)	0 / 875 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	0 / 931 (0.00%)	0 / 882 (0.00%)	0 / 875 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Henoch-Schonlein purpura			
subjects affected / exposed	0 / 931 (0.00%)	0 / 882 (0.00%)	0 / 875 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash macular			
subjects affected / exposed	1 / 931 (0.11%)	0 / 882 (0.00%)	0 / 875 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Petechiae			
subjects affected / exposed	0 / 931 (0.00%)	0 / 882 (0.00%)	0 / 875 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			

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

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

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

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

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

subjects affected / exposed	1 / 931 (0.11%)	0 / 882 (0.00%)	0 / 875 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpangina			
subjects affected / exposed	0 / 931 (0.00%)	1 / 882 (0.11%)	0 / 875 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 931 (0.00%)	1 / 882 (0.11%)	0 / 875 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 931 (0.00%)	0 / 882 (0.00%)	0 / 875 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 931 (0.00%)	0 / 882 (0.00%)	0 / 875 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Corynebacterium infection			
subjects affected / exposed	0 / 931 (0.00%)	0 / 882 (0.00%)	0 / 875 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endophthalmitis			
subjects affected / exposed	0 / 931 (0.00%)	0 / 882 (0.00%)	0 / 875 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
H1N1 influenza			
subjects affected / exposed	0 / 931 (0.00%)	0 / 882 (0.00%)	0 / 875 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

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

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

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

Notes: