Clinical trial results:
A phase IV, single-blind, randomised, controlled, multi-country study to evaluate the immunogenicity and safety of GSK's Infanrix hexa (DTPa-HBV-IPV/Hib) versus MCM Vaccine BV's Vaxelis (DTaP5 HBV IPV Hib), when administered intramuscularly according to a 2 , 4 and 12 month schedule in healthy infants and toddlers.

Summary

EudraCT number	2019-002988-10
Trial protocol	DE IT
Global end of trial date	10 November 2022

Results information

Result version number	v2 (current)
This version publication date	01 June 2024
First version publication date	24 May 2023
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	212645

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04535037
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals SA
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	GSK Response Center, GlaxoSmithKline Biologicals SA, 044 2089-904466, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline Biologicals SA, 044 2089-904466, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	12 January 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	10 November 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that the Hib response in DTPa-HBV-IPV/Hib investigational group is non-inferior to DTaP5 HBV IPV Hib comparator group, 1-month post-booster vaccination in terms of geometric mean concentrations (GMCs) and percentage of subjects with anti-polyribosylribitol phosphate (PRP) antibody concentrations equal to or above (≥) 5 microgram per milliliter (µg/mL).
To demonstrate that the Hib response in DTPa-HBV-IPV/Hib investigational group is superior to DTaP5 HBV IPV Hib comparator group, 1 month post-booster vaccination in terms of GMCs and percentage of subjects with anti-PRP antibody concentrations ≥5 µg/mL.A hierarchical procedure is used to these primary objectives.

Protection of trial subjects:

Subjects must be observed closely for at least 30 minutes after the administration of the vaccines. Appropriate medical treatment must be readily available during the observation period in case of anaphylaxis and/or syncope. Vaccines/products will be administered by qualified and trained personnel. Vaccines/products will be administered only to eligible participants who have no contraindications to any components of the vaccines/products. Participants will be followed-up for 31 days after the last vaccination/product administration.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 February 2021
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	Germany: 150
Country: Number of subjects enrolled	Italy: 20
Country: Number of subjects enrolled	Spain: 330
Worldwide total number of subjects	500
EEA total number of subjects	500

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0

Infants and toddlers (28 days-23 months)	500
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 500 participants were enrolled in the study.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind[1]
Roles blinded	Subject, Data analyst

Arms

Are arms mutually exclusive?	Yes
Arm title	Infanrix Hexa

Arm description:

All subjects in this group received 3 doses (2 primary doses and 1 booster dose) of DTPa-HBV-IPV/Hib vaccine co-administered with 3 doses of pneumococcal 13 valent conjugate vaccine at 2, 4, and 12 months of age.

Arm type	Experimental
Investigational medicinal product name	Infanrix hexa
Investigational medicinal product code	
Other name	DTPa-HBV-IPV/Hib
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses (1 each at 2, 4 and 12 months of age) of Infanrix hexa vaccine administered by intramuscular injection into the right thigh.

Investigational medicinal product name	Prevenar 13
Investigational medicinal product code	
Other name	Pneumococcal 13 valent conjugate vaccine
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses (1 each at 2, 4 and 12 months of age) of pneumococcal 13 valent conjugate vaccine administered by intramuscular injection into the left thigh.

Arm title	Vaxelis

Arm description:

All subjects in this group received 3 doses (2 primary doses and 1 booster dose) of DTaP5 HBV IPV Hib vaccine co-administered with 3 doses of pneumococcal 13 valent conjugate vaccine at 2, 4, and 12 months of age.

Arm type	Active comparator
Investigational medicinal product name	Prevenar 13
Investigational medicinal product code	
Other name	Pneumococcal 13 valent conjugate vaccine
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses (1 each at 2, 4 and 12 months of age) of pneumococcal 13 valent conjugate vaccine administered by intramuscular injection into the left thigh.

Investigational medicinal product name	Vaxelis
Investigational medicinal product code	
Other name	DTaP5 HBV IPV Hib
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses (1 each at 2, 4 and 12 months of age) of DTaP5 HBV IPV Hib vaccine administered by intramuscular injection into the right thigh.

Notes:

[1] - The number of roles blinded appears inconsistent with a single blinded trial. It is expected that there will be one role blinded in a single blind trial.
Justification: As per protocol, despite the fact that this is a single-blind study, the data management and biostatistics teams will remain blinded to the study treatment until after the final database lock.

Number of subjects in period 1	Infanrix Hexa	Vaxelis
Started	249	251
Completed	237	233
Not completed	12	18
Consent withdrawn by subject	8	9
Migrated / moved from the study area	1	4
Unspecified	2	5
Protocol deviation	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Infanrix Hexa
Reporting group description:	
All subjects in this group received 3 doses (2 primary doses and 1 booster dose) of DTPa-HBV-IPV/Hib vaccine co-administered with 3 doses of pneumococcal 13 valent conjugate vaccine at 2, 4, and 12 months of age.	
Reporting group title	Vaxelis
Reporting group description:	
All subjects in this group received 3 doses (2 primary doses and 1 booster dose) of DTaP5 HBV IPV Hib vaccine co-administered with 3 doses of pneumococcal 13 valent conjugate vaccine at 2, 4, and 12 months of age.	

Reporting group values	Infanrix Hexa	Vaxelis	Total
Number of subjects	249	251	500
Age categorical Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	249	251	500
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: Weeks			
arithmetic mean	8.6	8.6	
standard deviation	± 1.17	± 1.24	-
Sex: Female, Male Units: Participants			
Female	105	135	240
Male	144	116	260
Race/Ethnicity, Customized Units: Subjects			
Black or African American	1	2	3
American Indian or Alaska Native	1	2	3
Asian - Central / South Asian Heritage	0	1	1
Asian - East Asian Heritage	1	0	1
Asian - South East Asian Heritage	0	1	1
White - Arabic / North African Heritage	5	4	9
White - Caucasian / European Heritage	236	235	471
Other-Unspecified	5	6	11

End points

End points reporting groups

Reporting group title	Infanrix Hexa
Reporting group description:	
All subjects in this group received 3 doses (2 primary doses and 1 booster dose) of DTPa-HBV-IPV/Hib vaccine co-administered with 3 doses of pneumococcal 13 valent conjugate vaccine at 2, 4, and 12 months of age.	
Reporting group title	Vaxelis
Reporting group description:	
All subjects in this group received 3 doses (2 primary doses and 1 booster dose) of DTaP5 HBV IPV Hib vaccine co-administered with 3 doses of pneumococcal 13 valent conjugate vaccine at 2, 4, and 12 months of age.	

Primary: Anti-polyribosylribitol phosphate (anti-PRP) antibody concentrations at Month 11, based on Per protocol set (PPS)

End point title	Anti-polyribosylribitol phosphate (anti-PRP) antibody concentrations at Month 11, based on Per protocol set (PPS)
End point description:	
Anti-PRP antibody concentrations were presented as geometric mean concentrations (GMCs) and expressed in microgram per milliliter (µg/mL), as assessed by Enzyme-linked immunosorbent assay (ELISA). As specified in the Statistical Analysis Plan, for the co-primary objectives, only geometric mean was calculated for anti-PRP antibody concentration and was adjusted for DTPa vaccination of the mother (and thus, the 95% Confidence Interval [CI] is set as "9.999 to 9999"). The analysis was performed on the Per Protocol Set (PPS), which included all eligible subjects who received diphtheria, tetanus and acellular pertussis (DTPa)-combination study vaccines as per protocol, who had anti-PRP results post-vaccination, who complied with vaccination/blood draw intervals, without intercurrent conditions and without prohibited concomitant medication/vaccination and for whom immunogenicity data were available for specific timepoints.	
End point type	Primary
End point timeframe:	
At Month 11 (i.e., 1-month post-booster vaccination)	

End point values	Infanrix Hexa	Vaxelis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	211	218		
Units: µg/mL				
geometric mean (confidence interval 95%)	11.61 (9.999 to 9999)	12.66 (9.999 to 9999)		

Statistical analyses

Statistical analysis title	Non-inferiority of Infanrix Hexa vs Vaxelis
Statistical analysis description:	
Non-inferiority was demonstrated if the lower limit (LL) of the 2sided 95% CI on group GMC ratio (Infanrix Hexa over Vaxelis group) was above 0.5.	
Comparison groups	Infanrix Hexa v Vaxelis

Number of subjects included in analysis	429
Analysis specification	Pre-specified
Analysis type	non-inferiority[1]
Parameter estimate	Adjusted GMC Ratio
Point estimate	0.917
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	1.185

Notes:

[1] - The 95% CI for GMC ratio derived from an ANOVA model on log10 transformed concentration was used. GMC was adjusted for DTPA vaccination of the mother.

Primary: Anti-PRP antibody concentrations at Month 11, based on the Exposed Set (ES)

End point title	Anti-PRP antibody concentrations at Month 11, based on the Exposed Set (ES)[2]

End point description:

Anti-PRP antibody concentrations were presented as GMCs and expressed in µg/mL, as assessed by ELISA.
As specified in the Statistical Analysis Plan, for the co-primary objectives, only geometric mean was calculated for anti-PRP antibody concentration and was adjusted for DTPa vaccination of the mother (and thus, the 95%CI is set as "9.999 to 9999").
The analysis was performed on the Exposed Set (ES), which included all vaccinated subjects who were analysed according to the intervention they received at Dose 1 and for whom immunogenicity data were available for specific timepoints.

End point type	Primary

End point timeframe:

At Month 11 (i.e., 1-month post-booster vaccination)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Infanrix Hexa	Vaxelis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	175	228		
Units: µg/mL				
geometric mean (confidence interval 95%)	11.26 (9.999 to 9999)	12.85 (9.999 to 9999)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with anti-PRP antibody concentrations equal to or above (≥) 5 µg/mL at Month 11, based on PPS

End point title	Percentage of subjects with anti-PRP antibody concentrations equal to or above (≥) 5 µg/mL at Month 11, based on PPS

End point description:

The percentage of subjects with anti-PRP antibody concentrations ≥5 µg/mL was reported, as assessed by ELISA.

The analysis was performed on PPS, which included all eligible subjects who received all DTPa-combination study vaccines as per protocol, who had anti-PRP results post-vaccination, who complied with vaccination/blood draw intervals, without intercurrent conditions and without prohibited concomitant medication/vaccination.

End point type	Primary

End point timeframe:

At Month 11 (i.e., 1-month post-booster vaccination)

End point values	Infanrix Hexa	Vaxelis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	211	218		
Units: Percentage of Participants				
number (not applicable)	75.4	81.7		

Statistical analyses

Statistical analysis title	Non-inferiority of Infanrix Hexa vs Vaxelis

Statistical analysis description:

Non-inferiority was demonstrated if the non inferiority of anti-PRP GMC ratio was met and the LL of the 2 sided 95% CI on group difference in the percentage (Infanrix Hexa over Vaxelis group) was more than -10%.

Comparison groups	Infanrix Hexa v Vaxelis
Number of subjects included in analysis	429
Analysis specification	Pre-specified
Analysis type	non-inferiority[3]
Parameter estimate	Difference in Percentage
Point estimate	-6.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.1
upper limit	1.49

Notes:

[3] - The 2 sided 95% CI of group difference in seroconversion rate (Inv_group minus Com_group) was computed based on Miettinen and Nurminen method.

Primary: Percentage of subjects with anti-PRP antibody concentrations ≥ 5 µg/mL at Month 11, based on ES

End point title	Percentage of subjects with anti-PRP antibody concentrations ≥ 5 µg/mL at Month 11, based on ES[4]

End point description:

The percentage of subjects with anti-PRP antibody concentrations ≥5 µg/mL was reported, as assessed by ELISA.
The analysis was performed on the ES, which included all vaccinated subjects who were analysed according to the intervention they receive at Dose 1.

End point type	Primary

End point timeframe:

At Month 11 (i.e., 1-month post-booster vaccination)

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Infanrix Hexa	Vaxelis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	175	186		
Units: Percentage of Participants				
number (not applicable)	75.4	81.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with anti-PRP antibody concentration ≥ 0.15 µg/mL

End point title	Percentage of subjects with anti-PRP antibody concentration ≥ 0.15 µg/mL

End point description:

The percentage of subjects with anti-PRP antibody concentration equal to or above the threshold for short-term protection was reported. The threshold for short-term protection is 0.15 µg/mL.
The analysis was performed on PPS, which included all eligible subjects who received all DTPa-combination study vaccines as per protocol, who had anti-PRP results post-vaccination, who complied with vaccination/blood draw intervals, without intercurrent conditions and without prohibited concomitant medication/vaccination.

End point type	Secondary

End point timeframe:

At Month 3 (i.e., 1-month post-primary vaccination), Month 10 (i.e., pre-booster) and Month 11 (i.e., 1-month post-booster vaccination)

End point values	Infanrix Hexa	Vaxelis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	213	230		
Units: Percentage of Participants				
number (confidence interval 95%)				
At month 3 (N=213;230)	79.8 (73.79 to 84.99)	100 (98.41 to 100)		
At Month 10 (N=206;216)	61.2 (54.14 to 67.86)	94.4 (90.50 to 97.10)		
At Month 11 (N=211;218)	99.5 (97.39 to 99.99)	99.5 (97.47 to 99.99)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with anti-PRP antibody concentrations ≥ 1.0 µg/mL

End point title	Percentage of subjects with anti-PRP antibody concentrations ≥ 1.0 µg/mL

End point description:

The percentage of subjects with anti-PRP antibody concentration equal to or above the threshold for long-term protection was reported. The threshold for long-term protection is 1.0 µg/mL.
The analysis was performed on PPS, which included all eligible subjects who received all DTPa-combination study vaccines as per protocol, who had anti-PRP results post-vaccination, who complied with vaccination/blood draw intervals, without intercurrent conditions and without prohibited concomitant medication/vaccination.

End point type	Secondary

End point timeframe:

At Month 3 (i.e., 1-month post-primary vaccination), Month 10 (i.e., pre-booster) and Month 11 (i.e., 1-month post-booster vaccination)

End point values	Infanrix Hexa	Vaxelis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	213	230		
Units: Percentage of Participants				
number (confidence interval 95%)				
At Month 3 (N=213;230)	30.5 (24.41 to 37.18)	92.2 (87.91 to 95.30)		
At Month 10 (N=206;216)	13.1 (8.82 to 18.49)	69.0 (62.35 to 75.08)		
At Month 11 (N=211;218)	97.2 (93.91 to 98.95)	94.5 (90.58 to 97.12)		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-PRP antibody concentrations

End point title	Anti-PRP antibody concentrations

End point description:

Anti-PRP antibody concentrations were presented as GMCs and expressed in µg/mL, as assessed by ELISA.
The analysis was performed on PPS, which included all eligible subjects who received all DTPa-combination study vaccines as per protocol, who had anti-PRP results post-vaccination, who complied with vaccination/blood draw intervals, without intercurrent conditions and without prohibited concomitant medication/vaccination.

End point type	Secondary

End point timeframe:

At Month 3 (i.e., 1-month post-primary vaccination), Month 10 (i.e., pre-booster) and Month 11 (i.e., 1-month post-booster vaccination)

End point values	Infanrix Hexa	Vaxelis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	213	230		
Units: µg/mL				
geometric mean (confidence interval 95%)				
At Month 3 (N=213;230)	0.5 (0.41 to 0.62)	11.3 (9.35 to 13.60)		
At Month 10 (N=206;216)	0.2 (0.19 to 0.28)	1.9 (1.56 to 2.26)		
At Month 11 (N=211;218)	12.0 (9.96 to 14.34)	12.9 (10.75 to 15.55)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with unsolicited adverse events (AEs)

End point title	Number of subjects with unsolicited adverse events (AEs)

End point description:

AEs are defined as any untoward medical occurrence in a subject or subjects, temporally associated with the use of study treatment, whether or not considered related to the study treatment.
The analysis was performed on the ES, which included all vaccinated subjects who were analysed according to the intervention they receive at Dose 1.

End point type	Secondary

End point timeframe:

During the 31-day (Days 1-31) follow-up period after each vaccination (vaccines administered at 2, 4 and 12 months of age)

End point values	Infanrix Hexa	Vaxelis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	249	251		
Units: Participants	178	199		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serious adverse events (SAEs)

End point title	Number of subjects with serious adverse events (SAEs)

End point description:

An SAEs is defined as any untoward medical occurrence that, at any dose, result in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, resulted in disability/incapacity or was a congenital anomaly/birth defect.
The analysis was performed on the ES, which included all vaccinated subjects who were analysed according to the intervention they receive at Dose 1.

End point type	Secondary

End point timeframe:

Throughout the entire period of the study (from Day 1 up to study end [Month 11])

End point values	Infanrix Hexa	Vaxelis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	249	251		
Units: Participants	14	10		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Serious Adverse Events (SAEs) were collected throughout the entire period of the study (from Day 1 up to study end [Month 11]). Non Serious AEs (Other AEs) were collected 31 days after each vaccination (vaccines administered ot 2, 4 and 12 months of age).

Adverse event reporting additional description:

As number of occurrences of SAEs was not collected, number of subjects affected was reported instead.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups

Reporting group title	Infanrix Hexa

Reporting group description:

All subjects in this group received 3 doses (2 primary doses and 1 booster dose) of DTPa-HBV-IPV/Hib vaccine co-administered with 3 doses of pneumococcal 13 valent conjugate vaccine at 2, 4, and 12 months of age.

Reporting group title	Vaxelis

Reporting group description:

All subjects in this group received 3 doses (2 primary doses and 1 booster dose) of DTaP5 HBV IPV Hib vaccine co-administered with 3 doses of pneumococcal 13 valent conjugate vaccine at 2, 4, and 12 months of age.

Serious adverse events	Infanrix Hexa	Vaxelis	
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 249 (5.62%)	10 / 251 (3.98%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Investigations			
Enterovirus test positive			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (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			
Hydrocele			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Febrile convulsion			

subjects affected / exposed	1 / 249 (0.40%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	2 / 249 (0.80%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	2 / 249 (0.80%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Testicular torsion			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (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			
Respiratory failure			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia			

subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perirectal abscess			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parainfluenzae virus infection			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis norovirus			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiolitis			
subjects affected / exposed	2 / 249 (0.80%)	3 / 251 (1.20%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenovirus infection			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess neck			

subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	2 / 249 (0.80%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	1 / 249 (0.40%)	3 / 251 (1.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	0 / 249 (0.00%)	2 / 251 (0.80%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinovirus infection			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (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			
Hypophagia			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	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	Infanrix Hexa	Vaxelis	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	178 / 249 (71.49%)	199 / 251 (79.28%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma of skin			

subjects affected / exposed	2 / 249 (0.80%)	1 / 251 (0.40%)	
occurrences (all)	2	1	
Melanocytic naevus			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Vascular disorders			
Pallor			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
Injection site induration			
subjects affected / exposed	3 / 249 (1.20%)	0 / 251 (0.00%)	
occurrences (all)	3	0	
Administration site haemorrhage			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Administration site pain			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Crying			
subjects affected / exposed	5 / 249 (2.01%)	7 / 251 (2.79%)	
occurrences (all)	5	7	
Discomfort			
subjects affected / exposed	2 / 249 (0.80%)	4 / 251 (1.59%)	
occurrences (all)	2	4	
Fatigue			
subjects affected / exposed	2 / 249 (0.80%)	3 / 251 (1.20%)	
occurrences (all)	2	4	
Hyperpyrexia			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Induration			
subjects affected / exposed	1 / 249 (0.40%)	1 / 251 (0.40%)	
occurrences (all)	1	1	
Inflammation			

subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Injection site discomfort			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Injection site erythema			
subjects affected / exposed	6 / 249 (2.41%)	8 / 251 (3.19%)	
occurrences (all)	8	9	
Injection site haemorrhage			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Injection site oedema			
subjects affected / exposed	0 / 249 (0.00%)	2 / 251 (0.80%)	
occurrences (all)	0	2	
Injection site swelling			
subjects affected / exposed	7 / 249 (2.81%)	8 / 251 (3.19%)	
occurrences (all)	8	11	
Injection site warmth			
subjects affected / exposed	0 / 249 (0.00%)	2 / 251 (0.80%)	
occurrences (all)	0	2	
Irritability postvaccinal			
subjects affected / exposed	1 / 249 (0.40%)	1 / 251 (0.40%)	
occurrences (all)	1	1	
Malaise			
subjects affected / exposed	2 / 249 (0.80%)	3 / 251 (1.20%)	
occurrences (all)	3	3	
Nodule			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Pain			
subjects affected / exposed	1 / 249 (0.40%)	2 / 251 (0.80%)	
occurrences (all)	1	3	
Peripheral swelling			
subjects affected / exposed	4 / 249 (1.61%)	4 / 251 (1.59%)	
occurrences (all)	4	4	
Pyrexia			

subjects affected / exposed	103 / 249 (41.37%)	132 / 251 (52.59%)	
occurrences (all)	181	237	
Swelling			
subjects affected / exposed	1 / 249 (0.40%)	1 / 251 (0.40%)	
occurrences (all)	1	1	
Vaccination site erythema			
subjects affected / exposed	0 / 249 (0.00%)	2 / 251 (0.80%)	
occurrences (all)	0	2	
Vaccination site granuloma			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	2	
Vaccination site induration			
subjects affected / exposed	0 / 249 (0.00%)	2 / 251 (0.80%)	
occurrences (all)	0	2	
Vaccination site swelling			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Injection site pain			
subjects affected / exposed	6 / 249 (2.41%)	8 / 251 (3.19%)	
occurrences (all)	7	8	
Immune system disorders			
Allergy to arthropod bite			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Food allergy			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Milk allergy			
subjects affected / exposed	0 / 249 (0.00%)	3 / 251 (1.20%)	
occurrences (all)	0	3	
Reproductive system and breast disorders			
Genital labial adhesions			
subjects affected / exposed	2 / 249 (0.80%)	2 / 251 (0.80%)	
occurrences (all)	2	2	
Respiratory, thoracic and mediastinal disorders			

Bronchial hyperreactivity			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Bronchospasm			
subjects affected / exposed	0 / 249 (0.00%)	2 / 251 (0.80%)	
occurrences (all)	0	2	
Catarrh			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Cough			
subjects affected / exposed	7 / 249 (2.81%)	5 / 251 (1.99%)	
occurrences (all)	8	6	
Nasal congestion			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Pharyngeal inflammation			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Respiratory disorder			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Rhinorrhoea			
subjects affected / exposed	0 / 249 (0.00%)	4 / 251 (1.59%)	
occurrences (all)	0	4	
Psychiatric disorders			
Restlessness			
subjects affected / exposed	8 / 249 (3.21%)	13 / 251 (5.18%)	
occurrences (all)	14	18	
Agitation			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Anxiety			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Depressed mood			

subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Insomnia			
subjects affected / exposed	1 / 249 (0.40%)	2 / 251 (0.80%)	
occurrences (all)	1	2	
Irritability			
subjects affected / exposed	31 / 249 (12.45%)	37 / 251 (14.74%)	
occurrences (all)	48	56	
Sleep disorder			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Investigations			
Blood iron decreased			
subjects affected / exposed	1 / 249 (0.40%)	2 / 251 (0.80%)	
occurrences (all)	1	2	
Body temperature decreased			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Body temperature increased			
subjects affected / exposed	3 / 249 (1.20%)	5 / 251 (1.99%)	
occurrences (all)	3	5	
Injury, poisoning and procedural complications			
Nasal injury			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Arthropod bite			
subjects affected / exposed	1 / 249 (0.40%)	2 / 251 (0.80%)	
occurrences (all)	1	2	
Bite			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Electric shock			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Eye injury			

subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Face injury			
subjects affected / exposed	2 / 249 (0.80%)	0 / 251 (0.00%)	
occurrences (all)	2	0	
Hair-thread tourniquet syndrome			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Head injury			
subjects affected / exposed	2 / 249 (0.80%)	1 / 251 (0.40%)	
occurrences (all)	2	1	
Tibia fracture			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Vascular procedure complication			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Congenital, familial and genetic disorders			
Developmental hip dysplasia			
subjects affected / exposed	0 / 249 (0.00%)	2 / 251 (0.80%)	
occurrences (all)	0	2	
Microcephaly			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Odontogenic cyst			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Plagiocephaly			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Ankyloglossia congenital			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Cardiac disorders			

Pulmonary valve stenosis			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Nervous system disorders			
Head titubation			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Hypertonia			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Somnolence			
subjects affected / exposed	4 / 249 (1.61%)	5 / 251 (1.99%)	
occurrences (all)	4	5	
Syncope			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Lymphadenopathy			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Thrombocytosis			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Ear and labyrinth disorders			
Otorrhoea			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Eye disorders			
Astigmatism			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Dacryostenosis acquired			
subjects affected / exposed	3 / 249 (1.20%)	1 / 251 (0.40%)	
occurrences (all)	3	1	

Eye haematoma			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Eye irritation			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Hypermetropia			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Corneal erosion			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Frequent bowel movements			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Abdominal distension			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Abdominal pain			
subjects affected / exposed	6 / 249 (2.41%)	4 / 251 (1.59%)	
occurrences (all)	6	4	
Abdominal pain upper			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Anal erythema			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Anal fissure			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Constipation			
subjects affected / exposed	3 / 249 (1.20%)	9 / 251 (3.59%)	
occurrences (all)	3	10	
Dental cyst			

subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Diarrhoea			
subjects affected / exposed	15 / 249 (6.02%)	16 / 251 (6.37%)	
occurrences (all)	20	19	
Dry mouth			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Flatulence			
subjects affected / exposed	2 / 249 (0.80%)	4 / 251 (1.59%)	
occurrences (all)	2	4	
Gastrooesophageal reflux disease			
subjects affected / exposed	6 / 249 (2.41%)	4 / 251 (1.59%)	
occurrences (all)	6	4	
Infantile colic			
subjects affected / exposed	3 / 249 (1.20%)	2 / 251 (0.80%)	
occurrences (all)	3	2	
Nausea			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Odynophagia			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Oral pain			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Regurgitation			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Teething			
subjects affected / exposed	3 / 249 (1.20%)	1 / 251 (0.40%)	
occurrences (all)	4	2	
Vomiting			
subjects affected / exposed	8 / 249 (3.21%)	5 / 251 (1.99%)	
occurrences (all)	10	5	
Haematochezia			

subjects affected / exposed	2 / 249 (0.80%)	0 / 251 (0.00%)	
occurrences (all)	2	0	
Skin and subcutaneous tissue disorders			
Rash pruritic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Dermatitis			
subjects affected / exposed	7 / 249 (2.81%)	4 / 251 (1.59%)	
occurrences (all)	7	4	
Dermatitis atopic			
subjects affected / exposed	3 / 249 (1.20%)	1 / 251 (0.40%)	
occurrences (all)	3	1	
Dermatitis diaper			
subjects affected / exposed	6 / 249 (2.41%)	6 / 251 (2.39%)	
occurrences (all)	6	7	
Dry skin			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Eczema			
subjects affected / exposed	6 / 249 (2.41%)	5 / 251 (1.99%)	
occurrences (all)	7	5	
Erythema			
subjects affected / exposed	2 / 249 (0.80%)	3 / 251 (1.20%)	
occurrences (all)	2	3	
Papule			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Rash			
subjects affected / exposed	5 / 249 (2.01%)	3 / 251 (1.20%)	
occurrences (all)	5	3	
Rash macular			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Seborrhoeic dermatitis			
subjects affected / exposed	1 / 249 (0.40%)	1 / 251 (0.40%)	
occurrences (all)	1	1	

Urticaria			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Skin mass			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 249 (0.00%)	2 / 251 (0.80%)	
occurrences (all)	0	2	
Torticollis			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
Bronchitis			
subjects affected / exposed	6 / 249 (2.41%)	5 / 251 (1.99%)	
occurrences (all)	7	5	
Acarodermatitis			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Asymptomatic COVID-19			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Bronchiolitis			
subjects affected / exposed	4 / 249 (1.61%)	3 / 251 (1.20%)	
occurrences (all)	4	3	
Candida nappy rash			
subjects affected / exposed	2 / 249 (0.80%)	2 / 251 (0.80%)	
occurrences (all)	2	2	
Conjunctivitis			
subjects affected / exposed	14 / 249 (5.62%)	14 / 251 (5.58%)	
occurrences (all)	14	15	

COVID-19			
subjects affected / exposed	14 / 249 (5.62%)	9 / 251 (3.59%)	
occurrences (all)	14	9	
Croup infectious			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Ear infection			
subjects affected / exposed	2 / 249 (0.80%)	1 / 251 (0.40%)	
occurrences (all)	2	1	
Escherichia urinary tract infection			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Exanthema subitum			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Fungal skin infection			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Gastroenteritis			
subjects affected / exposed	9 / 249 (3.61%)	10 / 251 (3.98%)	
occurrences (all)	9	11	
Hand-foot-and-mouth disease			
subjects affected / exposed	2 / 249 (0.80%)	2 / 251 (0.80%)	
occurrences (all)	2	2	
Herpangina			
subjects affected / exposed	1 / 249 (0.40%)	2 / 251 (0.80%)	
occurrences (all)	1	2	
Impetigo			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Infected fistula			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Influenza			
subjects affected / exposed	2 / 249 (0.80%)	0 / 251 (0.00%)	
occurrences (all)	2	0	

Laryngitis			
subjects affected / exposed	5 / 249 (2.01%)	4 / 251 (1.59%)	
occurrences (all)	5	4	
Nasopharyngitis			
subjects affected / exposed	6 / 249 (2.41%)	14 / 251 (5.58%)	
occurrences (all)	7	14	
Oral candidiasis			
subjects affected / exposed	4 / 249 (1.61%)	5 / 251 (1.99%)	
occurrences (all)	4	5	
Otitis media			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Otitis media acute			
subjects affected / exposed	5 / 249 (2.01%)	6 / 251 (2.39%)	
occurrences (all)	5	6	
Paronychia			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Pharyngitis			
subjects affected / exposed	1 / 249 (0.40%)	3 / 251 (1.20%)	
occurrences (all)	1	3	
Pharyngotonsillitis			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Pilonidal disease			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Pneumonia			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Pyelonephritis			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Respiratory tract infection			
subjects affected / exposed	2 / 249 (0.80%)	6 / 251 (2.39%)	
occurrences (all)	2	8	

Respiratory tract infection viral			
subjects affected / exposed	3 / 249 (1.20%)	3 / 251 (1.20%)	
occurrences (all)	3	3	
Rhinitis			
subjects affected / exposed	2 / 249 (0.80%)	5 / 251 (1.99%)	
occurrences (all)	2	5	
Roseola			
subjects affected / exposed	1 / 249 (0.40%)	0 / 251 (0.00%)	
occurrences (all)	1	0	
Subglottic laryngitis			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Suspected COVID-19			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Tonsillitis			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Tonsillitis bacterial			
subjects affected / exposed	0 / 249 (0.00%)	1 / 251 (0.40%)	
occurrences (all)	0	1	
Upper respiratory tract infection			
subjects affected / exposed	18 / 249 (7.23%)	20 / 251 (7.97%)	
occurrences (all)	22	24	
Urinary tract infection			
subjects affected / exposed	1 / 249 (0.40%)	3 / 251 (1.20%)	
occurrences (all)	1	3	
Viral infection			
subjects affected / exposed	1 / 249 (0.40%)	4 / 251 (1.59%)	
occurrences (all)	1	4	
Viral rash			
subjects affected / exposed	1 / 249 (0.40%)	2 / 251 (0.80%)	
occurrences (all)	1	2	
Viral upper respiratory tract infection			
subjects affected / exposed	5 / 249 (2.01%)	6 / 251 (2.39%)	
occurrences (all)	6	6	

Respiratory syncytial virus infection subjects affected / exposed occurrences (all)	0 / 249 (0.00%) 0	1 / 251 (0.40%) 1	
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	4 / 249 (1.61%) 5	5 / 251 (1.99%) 5	
Hypoferritinaemia subjects affected / exposed occurrences (all)	1 / 249 (0.40%) 1	0 / 251 (0.00%) 0	
Iron deficiency subjects affected / exposed occurrences (all)	0 / 249 (0.00%) 0	1 / 251 (0.40%) 1	
Lactose intolerance subjects affected / exposed occurrences (all)	1 / 249 (0.40%) 1	0 / 251 (0.00%) 0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported