Clinical trial results:
A phase II, randomized, observer blind, controlled, multicenter study to assess immunogenicity and antibody persistence following vaccination with GSK's candidate combined measles, mumps, and rubella vaccine (MMR) versus M-M-R® II as a first dose, both administered subcutaneously at 12-15 months of age, concomitantly with hepatitis A vaccine (HAV), varicella vaccine (VV) and pneumococcal conjugate vaccine (PCV) but at separate sites.

Summary

EudraCT number	2011-005860-31
Trial protocol	Outside EU/EEA
Global end of trial date	18 June 2012

Results information

Result version number	v2 (current)
This version publication date	18 March 2018
First version publication date	31 July 2015
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	111870

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00861744
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, (44)2089 904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, (44)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	14 June 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 July 2010
Global end of trial reached?	Yes
Global end of trial date	18 June 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess GSK’s candidate MMR vaccine formulated with a range of mumps virus potencies, co-administered with HAV, VV and PCV in contrast to MMR-II co-administered with HAV, VV and PCV with respect to the seroresponse rate for antibodies to measles virus, mumps virus and rubella virus at Day 42.

Protection of trial subjects:

Vaccines were administered by qualified and trained personnel. Vaccines were administered only to eligible subjects that had no contraindications to any components of the vaccines.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 June 2009
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	23 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 1259
Worldwide total number of subjects	1259
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)	1259
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:

The study was divided in 3 phases: the active phase (up to Day 42), the extended safety follow-up (ESFU) phase (up to Day 180) and the antibody persistence phase (up to Day 730).

Pre-assignment

Screening details:

The number of subjects enrolled was 1259. 39 subjects were enrolled in the study but did not receive a subject number and were never vaccinated.

Pre-assignment period milestones

Number of subjects started	1259
Number of subjects completed	1220

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Not allocated to a study group: 35
Reason: Number of subjects	No vaccine received: 4

Period 1

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

Blinding implementation details:

The study was conducted in an observer blind manner in which the subject and the study personnel involved in the clinical evaluation of the subjects were blinded while other study personnel (investigator) were aware of the treatment allocation.

Arms

Are arms mutually exclusive?	Yes
Arm title	Priorix 1 Group

Arm description:

Subjects between 12 and 15 months of age at the time of study vaccination who received one dose of Priorix investigational vaccine (Lot 1) subcutaneously in the right upper arm. Subjects concomitantly received one dose of Havrix and Prevnar vaccines intramuscularly in the left and the right thigh, respectively and one dose of Varivax vaccine subcutaneously in the left upper arm. Subjects had previously received three doses of Prevnar vaccine within the first year of life with the third dose administered at least 30 days prior to enrollment and vaccination with study vaccines.

Arm type	Experimental
Investigational medicinal product name	Priorix
Investigational medicinal product code	
Other name	MMR
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subcutaneous injection, one dose, in the right upper arm.

Investigational medicinal product name	Varivax
Investigational medicinal product code	
Other name	VV
Pharmaceutical forms	Powder and solvent for suspension for injection

Routes of administration	Subcutaneous use
Dosage and administration details: Subcutaneous injection, one dose, in the left upper arm.	
Investigational medicinal product name	Havrix
Investigational medicinal product code	
Other name	HAV
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: Intramuscular injection, one dose, in the left thigh.	
Investigational medicinal product name	Prevnar
Investigational medicinal product code	
Other name	PCV
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: Intramuscular injection, one dose, in the right thigh.	
Arm title	Priorix 2 Group
Arm description: Subjects between 12 and 15 months of age at the time of study vaccination who received one dose of Priorix investigational vaccine (Lot 2) subcutaneously in the right upper arm. Subjects concomitantly received one dose of Havrix and Prevnar vaccines intramuscularly in the left and the right thigh, respectively and one dose of Varivax vaccine subcutaneously in the left upper arm. Subjects had previously received three doses of Prevnar vaccine within the first year of life with the third dose administered at least 30 days prior to enrollment and vaccination with study vaccines.	
Arm type	Experimental
Investigational medicinal product name	Priorix
Investigational medicinal product code	
Other name	MMR
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details: Subcutaneous injection, one dose, in the right upper arm.	
Investigational medicinal product name	Varivax
Investigational medicinal product code	
Other name	VV
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Subcutaneous use
Dosage and administration details: Subcutaneous injection, one dose, in the left upper arm.	
Investigational medicinal product name	Havrix
Investigational medicinal product code	
Other name	HAV
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: Intramuscular injection, one dose, in the left thigh.	
Investigational medicinal product name	Prevnar
Investigational medicinal product code	
Other name	PCV
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection, one dose, in the right thigh.

Arm title	Priorix 3 Group

Arm description:

Subjects between 12 and 15 months of age at the time of study vaccination who received one dose of Priorix investigational vaccine (Lot 3) subcutaneously in the right upper arm. Subjects concomitantly received one dose of Havrix and Prevnar vaccines intramuscularly in the left and the right thigh, respectively and one dose of Varivax vaccine subcutaneously in the left upper arm. Subjects had previously received three doses of Prevnar vaccine within the first year of life with the third dose administered at least 30 days prior to enrollment and vaccination with study vaccines.

Arm type	Experimental
Investigational medicinal product name	Priorix
Investigational medicinal product code	
Other name	MMR
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subcutaneous injection, one dose, in the right upper arm.

Investigational medicinal product name	Varivax
Investigational medicinal product code	
Other name	VV
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subcutaneous injection, one dose, in the left upper arm.

Investigational medicinal product name	Havrix
Investigational medicinal product code	
Other name	HAV
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection, one dose, in the left thigh.

Investigational medicinal product name	Prevnar
Investigational medicinal product code	
Other name	PCV
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection, one dose, in the right thigh.

Arm title	MMR-II Group

Arm description:

Subjects between 12 and 15 months of age at the time of study vaccination who randomly received one dose of one of three different commercially-available lot of M-M-R II (Merck and Co.) vaccine subcutaneously in the right upper arm. Subjects concomitantly received one dose of Havrix and Prevnar vaccines intramuscularly in the left and the right thigh, respectively and one dose of Varivax vaccine subcutaneously in the left upper arm. Subjects had previously received three doses of Prevnar vaccine within the first year of life with the third dose administered at least 30 days prior to enrollment and vaccination with study vaccines.

Arm type	Active comparator

Investigational medicinal product name	Varivax
Investigational medicinal product code	
Other name	VV
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Subcutaneous use
Dosage and administration details: Subcutaneous injection, one dose, in the left upper arm.	
Investigational medicinal product name	Havrix
Investigational medicinal product code	
Other name	HAV
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: Intramuscular injection, one dose, in the left thigh.	
Investigational medicinal product name	M-M-R II
Investigational medicinal product code	
Other name	MMR-II
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details: Subcutaneous injection, one dose, in the right upper arm.	
Investigational medicinal product name	Prevnar
Investigational medicinal product code	
Other name	PCV
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: Intramuscular injection, one dose, in the right thigh.	

Notes:

[1] - The roles blinded appear to be inconsistent with a double blind trial.

Justification: The study was conducted in an observer blind manner in which the subject and the study personnel involved in the clinical evaluation of the subjects were blinded while other study personnel (investigator) were aware of the treatment allocation.

Number of subjects in period 1[2]	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group
Started	304	304	304
Completed	287	275	280
Not completed	17	29	24
Consent withdrawn by subject	10	6	6
Adverse event, non-fatal	-	-	-
Lost to follow-up	7	19	17
Blood draws	-	-	-
Migration from study area	-	3	1
Protocol deviation	-	1	-

Number of subjects in period 1[2]	MMR-II Group
Started	308

Completed	275
Not completed	33
Consent withdrawn by subject	19
Adverse event, non-fatal	1
Lost to follow-up	12
Blood draws	1
Migration from study area	-
Protocol deviation	-

Notes:

[2] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: The number of subjects enrolled was 1259. 39 subjects were enrolled in the study but did not receive a subject number and were never vaccinated.

Baseline characteristics

Reporting groups	
Reporting group title	Priorix 1 Group
Reporting group description:	
Subjects between 12 and 15 months of age at the time of study vaccination who received one dose of Priorix investigational vaccine (Lot 1) subcutaneously in the right upper arm. Subjects concomitantly received one dose of Havrix and Prevnar vaccines intramuscularly in the left and the right thigh, respectively and one dose of Varivax vaccine subcutaneously in the left upper arm. Subjects had previously received three doses of Prevnar vaccine within the first year of life with the third dose administered at least 30 days prior to enrollment and vaccination with study vaccines.	
Reporting group title	Priorix 2 Group
Reporting group description:	
Subjects between 12 and 15 months of age at the time of study vaccination who received one dose of Priorix investigational vaccine (Lot 2) subcutaneously in the right upper arm. Subjects concomitantly received one dose of Havrix and Prevnar vaccines intramuscularly in the left and the right thigh, respectively and one dose of Varivax vaccine subcutaneously in the left upper arm. Subjects had previously received three doses of Prevnar vaccine within the first year of life with the third dose administered at least 30 days prior to enrollment and vaccination with study vaccines.	
Reporting group title	Priorix 3 Group
Reporting group description:	
Subjects between 12 and 15 months of age at the time of study vaccination who received one dose of Priorix investigational vaccine (Lot 3) subcutaneously in the right upper arm. Subjects concomitantly received one dose of Havrix and Prevnar vaccines intramuscularly in the left and the right thigh, respectively and one dose of Varivax vaccine subcutaneously in the left upper arm. Subjects had previously received three doses of Prevnar vaccine within the first year of life with the third dose administered at least 30 days prior to enrollment and vaccination with study vaccines.	
Reporting group title	MMR-II Group
Reporting group description:	
Subjects between 12 and 15 months of age at the time of study vaccination who randomly received one dose of one of three different commercially-available lot of M-M-R II (Merck and Co.) vaccine subcutaneously in the right upper arm. Subjects concomitantly received one dose of Havrix and Prevnar vaccines intramuscularly in the left and the right thigh, respectively and one dose of Varivax vaccine subcutaneously in the left upper arm. Subjects had previously received three doses of Prevnar vaccine within the first year of life with the third dose administered at least 30 days prior to enrollment and vaccination with study vaccines.	

Reporting group values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group
Number of subjects	304	304	304
Age categorical Units: Subjects			
Age continuous Units: months			
arithmetic mean	12.4	12.4	12.2
standard deviation	± 0.75	± 0.73	± 0.56
Gender categorical Units: Subjects			
Female	156	144	157
Male	148	160	147

Reporting group values	MMR-II Group	Total	
Number of subjects	308	1220	

Age categorical Units: Subjects			

Age continuous Units: months			
arithmetic mean	12.4		
standard deviation	± 0.75	-	
Gender categorical Units: Subjects			
Female	139	596	
Male	169	624	

End points

End points reporting groups

Reporting group title	Priorix 1 Group

Reporting group description:

Subjects between 12 and 15 months of age at the time of study vaccination who received one dose of Priorix investigational vaccine (Lot 1) subcutaneously in the right upper arm. Subjects concomitantly received one dose of Havrix and Prevnar vaccines intramuscularly in the left and the right thigh, respectively and one dose of Varivax vaccine subcutaneously in the left upper arm. Subjects had previously received three doses of Prevnar vaccine within the first year of life with the third dose administered at least 30 days prior to enrollment and vaccination with study vaccines.

Reporting group title	Priorix 2 Group

Reporting group description:

Subjects between 12 and 15 months of age at the time of study vaccination who received one dose of Priorix investigational vaccine (Lot 2) subcutaneously in the right upper arm. Subjects concomitantly received one dose of Havrix and Prevnar vaccines intramuscularly in the left and the right thigh, respectively and one dose of Varivax vaccine subcutaneously in the left upper arm. Subjects had previously received three doses of Prevnar vaccine within the first year of life with the third dose administered at least 30 days prior to enrollment and vaccination with study vaccines.

Reporting group title	Priorix 3 Group

Reporting group description:

Subjects between 12 and 15 months of age at the time of study vaccination who received one dose of Priorix investigational vaccine (Lot 3) subcutaneously in the right upper arm. Subjects concomitantly received one dose of Havrix and Prevnar vaccines intramuscularly in the left and the right thigh, respectively and one dose of Varivax vaccine subcutaneously in the left upper arm. Subjects had previously received three doses of Prevnar vaccine within the first year of life with the third dose administered at least 30 days prior to enrollment and vaccination with study vaccines.

Reporting group title	MMR-II Group

Reporting group description:

Subjects between 12 and 15 months of age at the time of study vaccination who randomly received one dose of one of three different commercially-available lot of M-M-R II (Merck and Co.) vaccine subcutaneously in the right upper arm. Subjects concomitantly received one dose of Havrix and Prevnar vaccines intramuscularly in the left and the right thigh, respectively and one dose of Varivax vaccine subcutaneously in the left upper arm. Subjects had previously received three doses of Prevnar vaccine within the first year of life with the third dose administered at least 30 days prior to enrollment and vaccination with study vaccines.

Primary: Number of subjects with Anti-measles virus antibody concentration equal to or above the cut-off-value.

End point title	Number of subjects with Anti-measles virus antibody concentration equal to or above the cut-off-value.[1]

End point description:

Anti-measles virus antibody cut-off-value assessed was ≥ 200 milli-International Units per milliliter (mIU/mL). The analysis was performed on seronegative subjects. Seronegative subjects are subjects with anti-measles virus antibody concentrations <150 mIU/mL prior to vaccination.

End point type	Primary

End point timeframe:

At Day 42 after administration of a dose of Priorix vaccine.

Notes:

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

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	247	240	240	249
Units: Subjects				
Subjects	245	236	236	248

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with Anti-mumps virus antibody titer equal to or above the cut-off-value.

End point title	Number of subjects with Anti-mumps virus antibody titer equal to or above the cut-off-value.[2]

End point description:

Anti-mumps virus antibody cut-off-value assessed was ≥ 51 Estimated Dose 50 (ED50). The analysis was performed on seronegative subjects. Seronegative subjects are subjects with anti-measles virus antibody concentrations <24 ED50 prior to vaccination.

End point type	Primary

End point timeframe:

At Day 42 after administration of a dose of Priorix vaccine.

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 scope of this end point was descriptive, no statistical hypothesis test was performed.

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	193	202	195	192
Units: Subjects				
Subjects	175	183	175	175

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with Anti-rubella virus antibody concentrations equal to or above the cut-off-value.

End point title	Number of subjects with Anti-rubella virus antibody concentrations equal to or above the cut-off-value.[3]

End point description:

Anti-rubella virus antibody cut-off-value assessed was ≥ 10 International Units per milliliter (IU/mL).

End point type	Primary

End point timeframe:

At Day 42 after administration of a dose of Priorix vaccine.

Notes:

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

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	247	238	239	249
Units: Subjects				
Subjects	244	235	233	249

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with Anti-varicella antibody concentration equal to or above the cut-off-value.

End point title	Number of subjects with Anti-varicella antibody concentration equal to or above the cut-off-value.

End point description:

Anti-varicella virus antibody cut-off-value assessed was ≥ 75 milli-International Units per milliliter (mIU/mL).

End point type	Secondary

End point timeframe:

At Day 42 after administration of a dose of Varivax vaccine.

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	245	238	240	246
Units: Subjects				
Subjects	240	230	230	241

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-measles virus antibody concentrations

End point title	Anti-measles virus antibody concentrations

End point description:

Antibody concentrations are expressed as Geometric Mean Concentrations (GMCs) in mIU/mL. The analysis was performed on seronegative subjects. Seronegative subjects are subjects with anti-measles virus antibody concentrations <150 mIU/mL prior to vaccination.

End point type	Secondary

End point timeframe:

At Day 42 after administration of a dose of Priorix vaccine.

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	247	240	240	249
Units: mIU/mL				
geometric mean (confidence interval 95%)				
mIU/mL	2798.7 (2544.8 to 3077.9)	2878.2 (2607.0 to 3177.7)	2593.1 (2350.3 to 2861.1)	2949.5 (2698.4 to 3224.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-mumps virus antibody concentrations

End point title	Anti-mumps virus antibody concentrations

End point description:

Antibody concentrations are expressed as Geometric Mean Titer (GMT). The analysis was performed on seronegative subjects. Seronegative subjects are subjects with antibody titer < 24 ED50 prior to vaccination.

End point type	Secondary

End point timeframe:

At Day 42 after administration of a dose of Priorix vaccine.

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	193	202	195	192
Units: Titers				
geometric mean (confidence interval 95%)				
Titers	242.0 (204.5 to 286.5)	265.0 (221.8 to 316.5)	253.4 (213.4 to 300.9)	267.6 (224.2 to 319.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-rubella virus antibody concentrations

End point title	Anti-rubella virus antibody concentrations

End point description:

Antibody concentrations are expressed as Geometric Mean Concentrations (GMCs) in IU/mL. The analysis was performed on seronegative subjects. Seronegative subjects are subjects with anti-rubella

virus antibody concentrations <4 IU/mL prior to vaccination.

End point type	Secondary

End point timeframe:

At Day 42 after administration of a dose of Priorix vaccine.

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	247	238	239	249
Units: IU/mL				
geometric mean (confidence interval 95%)				
IU/mL	72.2 (65.6 to 79.6)	77.7 (70.4 to 85.7)	68.2 (61.8 to 75.3)	89.4 (81.4 to 98.2)

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-S. pneumoniae antibody concentrations (by serotype).

End point title	Anti-S. pneumoniae antibody concentrations (by serotype).

End point description:

Antibody concentrations are expressed as Geometric Mean Concentrations (GMCs) in µg/mL.

End point type	Secondary

End point timeframe:

At Day 42 after vaccination

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	128	127	128	126
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-S.PNEU-4	3.57 (3.04 to 4.20)	3.72 (3.21 to 4.31)	3.40 (2.88 to 4.00)	3.80 (3.17 to 4.56)
Anti-S. PNEU-6B	5.68 (4.78 to 6.76)	5.87 (5.02 to 6.87)	5.41 (4.66 to 6.28)	7.22 (6.28 to 8.29)
Anti-S.PNEU 9V	6.56 (5.66 to 7.60)	7.30 (6.35 to 8.38)	5.81 (4.97 to 6.78)	7.80 (6.81 to 8.93)
Anti-S.PNEU-14	9.23 (8.03 to 10.61)	8.33 (7.30 to 9.51)	7.58 (6.55 to 8.76)	7.97 (6.95 to 9.14)
Anti-S.PNEU-18 C	6.20 (5.30 to 7.26)	6.62 (5.76 to 7.60)	6.15 (5.25 to 7.21)	6.73 (5.74 to 7.91)
Anti-S.PNEU-19 F	2.42 (2.05 to 2.85)	2.46 (2.11 to 2.88)	2.34 (2.00 to 2.73)	2.59 (2.23 to 3.00)
Anti-S.PNEU-23 F	9.34 (7.76 to 11.25)	9.27 (7.82 to 10.99)	8.33 (6.88 to 10.10)	11.49 (9.67 to 13.66)

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-varicella antibody concentrations.

End point title	Anti-varicella antibody concentrations.

End point description:

Antibody concentrations are expressed as Geometric Mean Titers (GMT). The analysis was performed on seronegative subjects. Seronegative subjects are subjects with antibody concentration < 25 mIU/mL prior to vaccination.

End point type	Secondary

End point timeframe:

At Day 42 after administration of a dose of Varivax vaccine.

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	245	238	240	246
Units: mIU/mL				
geometric mean (confidence interval 95%)				
mIU/mL	245.5 (229.0 to 263.3)	235.2 (217.4 to 254.4)	236.0 (218.0 to 255.5)	255.9 (240.4 to 272.4)

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-hepatitis A virus antibody concentrations.

End point title	Anti-hepatitis A virus antibody concentrations.

End point description:

Antibody concentrations are expressed as Geometric Mean Concentrations (GMCs) in mIU/mL. The analysis was performed on seronegative subjects. Seronegative subjects are subjects with anti-hepatitis A virus antibody concentrations <15 mIU/mL prior to vaccination.

End point type	Secondary

End point timeframe:

At Day 42 after administration of a dose of Havrix vaccine.

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	117	112	111	124
Units: mIU/mL				
geometric mean (confidence interval 95%)				
mIU/mL	33.8 (28.8 to 39.6)	39.2 (33.1 to 46.5)	39.4 (32.7 to 47.5)	42.1 (35.8 to 49.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with Anti-hepatitis A antibody concentrations equal to or above the cut-off-value.

End point title	Number of subjects with Anti-hepatitis A antibody concentrations equal to or above the cut-off-value.

End point description:

Anti-hepatitis A antibody cut-off-value assessed was ≥15 milli-International Units per milliliter (mIU/mL).

End point type	Secondary

End point timeframe:

At Day 42 after administration of a dose of Havrix vaccine.

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	117	112	111	124
Units: Subjects				
Subjects	98	99	94	110

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-S. pneumoniae antibody concentrations (by serotype).

End point title	Anti-S. pneumoniae antibody concentrations (by serotype).

End point description:

Antibody concentrations are expressed as Geometric Mean Concentrations (GMCs) in µg/mL.

End point type	Secondary

End point timeframe:

At Day 0 before vaccination

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	129	130	130	119
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-S.PNEU-4	0.54 (0.46 to 0.65)	0.61 (0.52 to 0.72)	0.67 (0.58 to 0.78)	0.67 (0.56 to 0.81)
Anti-S.PNEU-6B	0.53 (0.43 to 0.66)	0.57 (0.46 to 0.70)	0.52 (0.43 to 0.64)	0.67 (0.56 to 0.80)
Anti-S.PNEU-9V	1.01 (0.85 to 1.20)	1.13 (0.97 to 1.32)	1.04 (0.88 to 1.23)	1.26 (1.06 to 1.49)
Anti-S.PNEU-14	3.01 (2.60 to 3.47)	2.82 (2.42 to 3.28)	2.54 (2.21 to 2.92)	2.76 (2.38 to 3.20)
Anti-S.PNEU-18C	0.88 (0.74 to 1.03)	0.97 (0.83 to 1.13)	0.97 (0.83 to 1.14)	1.00 (0.86 to 1.15)
Anti-S.PNEU-19F	0.40 (0.32 to 0.50)	0.40 (0.33 to 0.50)	0.44 (0.36 to 0.53)	0.45 (0.37 to 0.56)
Anti-S.PNEU-23 F	0.64 (0.51 to 0.82)	0.63 (0.51 to 0.77)	0.65 (0.52 to 0.81)	0.85 (0.67 to 1.08)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-measles virus antibody concentration equal to or above the cut-off-value

End point title	Number of subjects with anti-measles virus antibody concentration equal to or above the cut-off-value

End point description:

Anti-measles virus antibody cut-off-value assessed was ≥ 200 milli-International Units per milliliter (mIU/mL).

End point type	Secondary

End point timeframe:

At 1 year post-vaccination

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	213	215	218	210
Units: Subjects				
Subjects	211	211	218	209

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-measles virus antibody concentration

equal to or above the cut-off-value	
End point title	Number of subjects with anti-measles virus antibody concentration equal to or above the cut-off-value

End point description:

Anti-measles virus antibody cut-off-value assessed was ≥ 200 milli-International Units per milliliter (mIU/mL).

End point type	Secondary

End point timeframe:

At 2 years post-vaccination

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	171	159	169	166
Units: Subjects				
Subjects	171	159	168	166

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-measles virus antibody concentrations	
End point title	Anti-measles virus antibody concentrations

End point description:

Antibody concentrations are expressed as Geometric Mean Concentrations (GMCs) in mIU/mL. The analysis was performed on seronegative subjects. Seronegative subjects are subjects with anti-measles virus antibody concentrations <150 mIU/mL prior to vaccination.

End point type	Secondary

End point timeframe:

At 2 years post-vaccination

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	171	159	169	166
Units: mIU/mL				
geometric mean (confidence interval 95%)				
mIU/mL	3361.1 (2922.3 to 3865.6)	3963.8 (3479.3 to 4515.7)	3360.3 (2923.3 to 3862.7)	4022.1 (3507.7 to 4611.9)

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-measles virus antibody concentrations

End point title	Anti-measles virus antibody concentrations

End point description:

Antibody concentrations were expressed as Geometric Mean Concentrations (GMCs) in mIU/mL. The analysis was performed on seronegative subjects. Seronegative subjects are subjects with anti-measles virus antibody concentrations <150 mIU/mL prior to vaccination.

End point type	Secondary

End point timeframe:

At 1 year post-vaccination

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	213	215	218	210
Units: mIU/mL				
geometric mean (confidence interval 95%)				
mIU/mL	3224.3 (2840.1 to 3660.5)	3708.2 (3226.2 to 4262.2)	3534.7 (3139.9 to 3979.1)	3828.1 (3371.3 to 4346.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting investigator-confirmed measles/rubella-like rash and varicella-like rash.

End point title	Number of subjects reporting investigator-confirmed measles/rubella-like rash and varicella-like rash.

End point description:

End point type	Secondary

End point timeframe:

During the 43-day (Days 0-42) post-vaccination period

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	283	275	283	277
Units: Subjects				
Varicella like	0	4	0	0
Measles/Rubella like	6	7	5	5

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting febrile convulsions

End point title	Number of subjects reporting febrile convulsions

End point description:

Timing of febrile convulsions: events occured on Day 29 in the Priorix 2 Group and Day 0 in the MMR II Group. All cases of febrile convulsions were case of meningism.

End point type	Secondary

End point timeframe:

During the 43-day (Days 0-42) post-vaccination period

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	283	275	283	277
Units: Subjects				
Subjects	0	1	0	1

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-mumps virus antibody titers (enhanced Plaque Reduction Neutralization (PRN))

End point title	Anti-mumps virus antibody titers (enhanced Plaque Reduction Neutralization (PRN))

End point description:

Antibody titers were expressed as Geometric Mean Titer (GMT). The analysis was performed on seronegative subjects. Seronegative subjects are subjects with antibody titer < 24 ED50 prior to vaccination.

End point type	Secondary

End point timeframe:

At 1 year post-vaccination

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	189	186	189	183
Units: Titers				
geometric mean (confidence interval 95%)				
Titers	162.8 (141.8 to 186.9)	188.3 (162.4 to 218.3)	176.2 (152.6 to 203.3)	185.5 (163.5 to 210.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting other rash.

End point title	Number of subjects reporting other rash.

End point description:

Other rash = not confirmed by the investigator to be either measles/rubella-like or varicella-like in nature

End point type	Secondary

End point timeframe:

During the 43-day (Days 0-42) post-vaccination period

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	283	275	283	277
Units: Subjects				
Localized or generalized	72	74	60	60
With fever	26	29	23	23
Grade 3	11	10	6	6
Related	9	14	6	6

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-mumps virus antibody titers above the cut-off value (enhanced PRN)

End point title	Number of subjects with anti-mumps virus antibody titers above the cut-off value (enhanced PRN)

End point description:

Anti-mumps virus antibody cut-off-value assessed was ≥ 51 ED50.

End point type	Secondary

End point timeframe:

At 1 year post-vaccination

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	189	186	189	183
Units: Subjects				
Subjects	169	170	171	170

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with Anti-rubella virus antibody concentrations equal to or above the cut-off-value.

End point title	Number of subjects with Anti-rubella virus antibody concentrations equal to or above the cut-off-value.

End point description:

Anti-rubella virus antibody cut-off-value assessed was ≥ 10 International Units per milliliter (IU/mL). The analysis was performed on seronegative subjects. Seronegative subjects are subjects with anti-rubella virus antibody concentrations <4 IU/mL prior to vaccination.

End point type	Secondary

End point timeframe:

At 1 year post-vaccination

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	213	214	218	210
Units: Subjects				
Subjects	212	213	217	210

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-rubella virus antibody concentrations equal to or above the cut-off-value.

End point title	Number of subjects with anti-rubella virus antibody concentrations equal to or above the cut-off-value.

End point description:

Anti-rubella virus antibody cut-off-value assessed was ≥ 10 International Units per milliliter (IU/mL).

End point type	Secondary

End point timeframe:

At 2 years post-vaccination

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	171	158	168	166
Units: Subjects				
Subjects	171	158	168	166

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-rubella virus antibody concentrations

End point title	Anti-rubella virus antibody concentrations

End point description:

Antibody concentrations are expressed as Geometric Mean Concentrations (GMCs) in IU/mL. The analysis was performed on seronegative subjects. Seronegative subjects are subjects with anti-rubella virus antibody concentrations <4 IU/mL prior to vaccination.

End point type	Secondary

End point timeframe:

At 1 year post-vaccination

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	213	214	218	210
Units: IU/mL				
geometric mean (confidence interval 95%)				
IU/mL	138.1 (125.3 to 152.2)	145.4 (132.0 to 160.1)	136.5 (123.5 to 150.9)	166.8 (151.5 to 183.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-rubella virus antibody concentrations

End point title	Anti-rubella virus antibody concentrations

End point description:

Antibody concentrations are expressed as Geometric Mean Concentrations (GMCs) in IU/mL. The analysis was performed on seronegative subjects. Seronegative subjects are subjects with anti-rubella virus antibody concentrations <4 IU/mL prior to vaccination.

End point type	Secondary

End point timeframe:

At 2 years post-vaccination

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	171	158	168	166
Units: IU/mL				
geometric mean (confidence interval 95%)				
IU/mL	78.0 (69.7 to 87.2)	79.5 (71.7 to 88.2)	81.7 (73.8 to 90.4)	93.1 (83.6 to 103.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting fever.

End point title	Number of subjects reporting fever.

End point description:

fever is assessed for temperature ≥38°C/100.4°F and >39.5°C/103.1°F as measured rectally.

End point type	Secondary

End point timeframe:

During the 15-day (Days 0-14) and 43 days (Days 0-42) post-vaccination period

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	283	275	283	277
Units: Subjects				
Day 15 (N= 283; 275; 283; 277) ≥38.0°C	65	79	64	56
Day 15 (N= 283; 275; 283; 277) >39.5°C	10	7	9	8
Day 43 (N= 283; 275; 283; 277) ≥38.0°C	103	104	104	85
Day 43 (N= 283; 275; 283; 277) >39.5°C	20	14	18	13

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited local symptoms.

End point title	Number of subjects with solicited local symptoms.

End point description:

Solicited local symptoms assessed were pain, redness and swelling.

End point type	Secondary

End point timeframe:

During the 4-day (Days 0-3) post-vaccination period

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	282	274	282	274
Units: Subjects				
Pain	70	70	79	67
Redness	45	47	41	47
Swelling	20	26	19	15

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting Medically attended visit (MAEs)

End point title	Number of subjects reporting Medically attended visit (MAEs)

End point description:

MAEs were defined as events for which the subject received medical attention defined as hospitalization, an emergency room visit, or a visit to or from medical personnel (medical doctor) for any reason. Any MAE(s) = Occurrence of any MAE(s) regardless of intensity grade or relation to vaccination.

End point type	Secondary

End point timeframe:

During the 43-day (Days 0-42) post-vaccination period

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	304	304	304	308
Units: Subjects				
Subjects	99	99	97	107

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:

An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any = the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination.

End point type	Secondary

End point timeframe:

During the 43-day (Days 0-42) post-vaccination period

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	304	304	304	308
Units: Subjects				
Subjects	170	153	164	169

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting investigator-confirmed parotid/salivary gland swelling.

End point title	Number of subjects reporting investigator-confirmed parotid/salivary gland swelling.

End point description:

Swelling with accompanying general symptoms

End point type	Secondary

End point timeframe:

During the 43-day (Days 0-42) post-vaccination period

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	283	275	283	277
Units: Subjects				
Subjects	3	3	5	2

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited general symptoms.

End point title	Number of subjects with solicited general symptoms.

End point description:

Assessed solicited general symptoms were drowsiness, irritability and loss of appetite. Any = occurrence of the symptom regardless of intensity grade.

End point type	Secondary

End point timeframe:

During the 15-day (Days 0-14) post-vaccination period

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	283	275	283	277
Units: Subjects				
Any drowsiness	133	106	113	109
Any irritability	180	141	150	153
Any loss of appetite	111	77	110	94

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting new onset chronic illnesses (NOCIs).

End point title	Number of subjects reporting new onset chronic illnesses (NOCIs).

End point description:

NOCIs included autoimmune disorders, asthma, type I diabetes, allergies.

End point type	Secondary

End point timeframe:

From Day 0 to Day 180 after vaccination

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	304	304	304	308
Units: Subjects				
Subjects	5	2	4	2

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

SAEs assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization, result in disability/incapacity or are a congenital anomaly/birth defect in the offspring of a study subject.

End point type	Secondary

End point timeframe:

From Day 0 to Day 180 after vaccination

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	304	304	304	308
Units: Subjects				
Subjects	1	6	7	9

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting serious adverse events (SAEs).

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

End point description:

SAEs assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization, result in disability/incapacity or are congenital anomaly/birth defect in the offspring of a study subject.

End point type	Secondary

End point timeframe:

From Day 180 to Day 730 after vaccination

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	304	304	304	308
Units: Subjects				
Subjects	0	0	0	1

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting conditions prompting emergency room (ER) visits.

End point title	Number of subjects reporting conditions prompting emergency room (ER) visits.

End point description:

End point type	Secondary

End point timeframe:

From Day 0 to Day 180 after vaccination

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	304	304	304	308
Units: Subjects				
Subjects	27	28	22	26

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-mumps virus antibody titers (unenhanced PRN)

End point title	Anti-mumps virus antibody titers (unenhanced PRN)

End point description:

Antibody titers were expressed as Geometric Mean Titer (GMT).

End point type	Secondary

End point timeframe:

At 1 year post-vaccination

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	196	205	211	195
Units: Titer				
geometric mean (confidence interval 95%)				
Titer	31.0 (24.1 to 39.9)	46.1 (36.2 to 58.7)	39.3 (31.0 to 50.0)	46.6 (36.6 to 59.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-mumps virus antibody titers above the cut-off value (unenhanced PRN)

End point title	Number of subjects with anti-mumps virus antibody titers above the cut-off value (unenhanced PRN)

End point description: Anti-mumps virus antibody cut-off-value assessed was ≥ 4 Estimated Dose 50 (ED50).	
End point type	Secondary
End point timeframe: At 1 year post-vaccination	

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	196	205	211	195
Units: Subjects				
Subjects	173	186	184	173

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-mumps virus antibody titers (unenhanced PRN)

End point title	Anti-mumps virus antibody titers (unenhanced PRN)
End point description: Antibody concentrations are expressed as Geometric Mean Titer (GMT).	
End point type	Secondary
End point timeframe: At 2 years post-vaccination	

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	157	144	157	152
Units: Titer				
geometric mean (confidence interval 95%)				
Titer	43.4 (33.4 to 56.3)	48.9 (37.7 to 63.5)	57.4 (45.7 to 72.2)	60.7 (47.6 to 77.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-mumps virus antibody titers above the cut-off value (unenhanced PRN)

End point title	Number of subjects with anti-mumps virus antibody titers above the cut-off value (unenhanced PRN)

End point description:	
Anti-mumps virus antibody cut-off-value assessed was ≥ 4 Estimated Dose 50 (ED50).	
End point type	Secondary
End point timeframe:	
At 2 years post-vaccination	

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	157	144	157	152
Units: Subjects				
Subjects	144	134	152	144

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-mumps virus antibody concentrations (Pharmaceutical Product Development (PPD) ELISA)

End point title	Anti-mumps virus antibody concentrations (Pharmaceutical Product Development (PPD) ELISA)
End point description:	
Antibody concentrations are expressed as Geometric Mean Concentrations (GMC) in ELISA units per milliliter (EU/mL). The analysis was performed on seronegative subjects. Seronegative subjects are subjects with anti-rubella virus antibody concentrations <5 EU/mL prior to vaccination.	
End point type	Secondary
End point timeframe:	
At 1 year post-vaccination	

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	170	173	179	170
Units: EU/mL				
geometric mean (confidence interval 95%)				
EU/mL	47.3 (39.2 to 57.1)	42.9 (36.4 to 50.6)	42.5 (35.9 to 50.3)	58.6 (50.6 to 67.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-mumps virus antibody concentrations

above the cut-off value (PPD ELISA)	
End point title	Number of subjects with anti-mumps virus antibody concentrations above the cut-off value (PPD ELISA)
End point description:	
Anti-mumps virus antibody cut-off-value assessed was ≥ 10 ELISA units per milliliter (EU/mL)	
End point type	Secondary
End point timeframe:	
At 1 year post-vaccination	

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	170	173	179	170
Units: Subjects				
Subjects	155	159	162	164

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-mumps virus antibody concentrations (PPD ELISA)	
End point title	Anti-mumps virus antibody concentrations (PPD ELISA)
End point description:	
Antibody concentrations are expressed as Geometric Mean Concentrations (GMC) in ELISA units per milliliter (EU/mL). The analysis was performed on seronegative subjects. Seronegative subjects are subjects with anti-rubella virus antibody concentrations <5 EU/mL prior to vaccination.	
End point type	Secondary
End point timeframe:	
At 2 years post-vaccination	

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	136	130	141	140
Units: EU/mL				
geometric mean (confidence interval 95%)				
EU/mL	47.8 (40.2 to 56.9)	50.2 (42.1 to 59.9)	54.0 (46.1 to 63.3)	59.2 (50.1 to 70.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-mumps virus antibody concentrations above the cut-off value (PPD ELISA)

End point title	Number of subjects with anti-mumps virus antibody concentrations above the cut-off value (PPD ELISA)

End point description:

Anti-mumps virus antibody cut-off-value assessed was ≥ 10 ELISA units per milliliter (EU/mL)

End point type	Secondary

End point timeframe:

At 2 years post-vaccination

End point values	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group	MMR-II Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	136	130	141	140
Units: Subjects				
Subjects	128	125	136	134

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Solicited symptoms: During the 4-day (Days 0-3) post-vaccination period. Unsolicited AEs: During the 43-day (Days 0-42) post vaccination period. SAEs: the entire study period (Day 0-Day 730).

Adverse event reporting additional description:

Solicited symptoms were only assessed on subjects returning the symptom sheet.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	16.0

Reporting groups

Reporting group title	Priorix 1 Group

Reporting group description:

Subjects between 12 and 15 months of age at the time of study vaccination who received one dose of Priorix investigational vaccine (Lot 1) subcutaneously in the right upper arm. Subjects concomitantly received one dose of Havrix and Prevnar vaccines intramuscularly in the left and the right thigh, respectively and one dose of Varivax vaccine subcutaneously in the left upper arm. Subjects had previously received three doses of Prevnar vaccine within the first year of life with the third dose administered at least 30 days prior to enrollment and vaccination with study vaccines.

Reporting group title	Priorix 2 Group

Reporting group description:

Subjects between 12 and 15 months of age at the time of study vaccination who received one dose of Priorix investigational vaccine (Lot 2) subcutaneously in the right upper arm. Subjects concomitantly received one dose of Havrix and Prevnar vaccines intramuscularly in the left and the right thigh, respectively and one dose of Varivax vaccine subcutaneously in the left upper arm. Subjects had previously received three doses of Prevnar vaccine within the first year of life with the third dose administered at least 30 days prior to enrollment and vaccination with study vaccines.

Reporting group title	Priorix 3 Group

Reporting group description:

Subjects between 12 and 15 months of age at the time of study vaccination who received one dose of Priorix investigational vaccine (Lot 3) subcutaneously in the right upper arm. Subjects concomitantly received one dose of Havrix and Prevnar vaccines intramuscularly in the left and the right thigh, respectively and one dose of Varivax vaccine subcutaneously in the left upper arm. Subjects had previously received three doses of Prevnar vaccine within the first year of life with the third dose administered at least 30 days prior to enrollment and vaccination with study vaccines.

Reporting group title	MMR-II Group

Reporting group description:

Subjects between 12 and 15 months of age at the time of study vaccination who randomly received one dose of one of three different commercially-available lot of M-M-R II (Merck and Co.) vaccine subcutaneously in the right upper arm. Subjects concomitantly received one dose of Havrix and Prevnar vaccines intramuscularly in the left and the right thigh, respectively and one dose of Varivax vaccine subcutaneously in the left upper arm. Subjects had previously received three doses of Prevnar vaccine within the first year of life with the third dose administered at least 30 days prior to enrollment and vaccination with study vaccines.

Serious adverse events	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 304 (0.33%)	6 / 304 (1.97%)	7 / 304 (2.30%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Nephroblastoma			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
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			
Extremity necrosis			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (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			
Ataxia			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (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
Febrile convulsion			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
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			
Idiopathic thrombocytopenic purpura			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (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
Lymphadenitis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Influenza like illness			

subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Intussusception			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchial hyperreactivity			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
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 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal congestion			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
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			
Petechiae			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
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			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
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			
Bronchiolitis			
subjects affected / exposed	1 / 304 (0.33%)	1 / 304 (0.33%)	0 / 304 (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
Bronchitis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coxsackie viral infection			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
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 viral			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
H1n1 influenza			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
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 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
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 infection			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (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
Upper respiratory tract infection			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
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	MMR-II Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 308 (3.25%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Nephroblastoma			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Vascular disorders			
Extremity necrosis			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Febrile convulsion			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Idiopathic thrombocytopenic purpura			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Leukocytosis			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphadenitis			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Influenza like illness			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyrexia			

subjects affected / exposed	0 / 308 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Intussusception			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Bronchial hyperreactivity			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypoxia			
subjects affected / exposed	2 / 308 (0.65%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Nasal congestion			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Petechiae			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rash			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Bronchiolitis			

subjects affected / exposed	2 / 308 (0.65%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Bronchitis				
subjects affected / exposed	1 / 308 (0.32%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coxsackie viral infection				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis viral				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
H1n1 influenza				
subjects affected / exposed	1 / 308 (0.32%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	1 / 308 (0.32%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pharyngotonsillitis				
subjects affected / exposed	1 / 308 (0.32%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia				

subjects affected / exposed	1 / 308 (0.32%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia respiratory syncytial viral			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory syncytial virus infection			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Staphylococcal infection			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Priorix 1 Group	Priorix 2 Group	Priorix 3 Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	240 / 304 (78.95%)	216 / 304 (71.05%)	219 / 304 (72.04%)
Vascular disorders			
Pallor			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Surgical and medical procedures			

Sinus operation			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	1 / 304 (0.33%)
occurrences (all)	0	1	1
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Crying			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	2
Discomfort			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	1	0	1
Hyperpyrexia			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Injection site bruising			
subjects affected / exposed	3 / 304 (0.99%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	3	0	1
Injection site erythema			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed	1 / 304 (0.33%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	1	1	0
Injection site mass			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Injection site reaction			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Injection site swelling			

subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Local swelling			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	1	0	1
Oedema peripheral			
subjects affected / exposed	1 / 304 (0.33%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	1	1	0
Pain			
subjects affected / exposed	72 / 304 (23.68%)	70 / 304 (23.03%)	79 / 304 (25.99%)
occurrences (all)	72	70	79
Pyrexia			
subjects affected / exposed	1 / 304 (0.33%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	1	1	0
Swelling			
subjects affected / exposed	22 / 304 (7.24%)	26 / 304 (8.55%)	20 / 304 (6.58%)
occurrences (all)	22	26	20
Vessel puncture site bruise			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 304 (0.00%)	2 / 304 (0.66%)	1 / 304 (0.33%)
occurrences (all)	0	2	2
Milk allergy			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	0	0	0
Multiple allergies			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	1 / 304 (0.33%)
occurrences (all)	0	1	1
Seasonal allergy			
subjects affected / exposed	1 / 304 (0.33%)	1 / 304 (0.33%)	1 / 304 (0.33%)
occurrences (all)	1	1	1
Reproductive system and breast disorders			

Genital cyst			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Gynaecomastia			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Penile adhesion			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Vaginal discharge			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Adenoidal hypertrophy			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Asthma			
subjects affected / exposed	3 / 304 (0.99%)	0 / 304 (0.00%)	2 / 304 (0.66%)
occurrences (all)	3	0	2
Bronchial hyperreactivity			
subjects affected / exposed	2 / 304 (0.66%)	1 / 304 (0.33%)	3 / 304 (0.99%)
occurrences (all)	2	1	3
Cough			
subjects affected / exposed	25 / 304 (8.22%)	21 / 304 (6.91%)	16 / 304 (5.26%)
occurrences (all)	28	24	17
Dyspnoea			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	1 / 304 (0.33%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	1	1	0
Increased upper airway secretion			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Nasal congestion			

subjects affected / exposed	7 / 304 (2.30%)	13 / 304 (4.28%)	9 / 304 (2.96%)
occurrences (all)	8	13	9
Nasal disorder			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	2 / 304 (0.66%)	0 / 304 (0.00%)	2 / 304 (0.66%)
occurrences (all)	2	0	2
Respiratory disorder			
subjects affected / exposed	1 / 304 (0.33%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	1	1	0
Rhinitis allergic			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	1 / 304 (0.33%)
occurrences (all)	0	1	1
Rhinorrhoea			
subjects affected / exposed	22 / 304 (7.24%)	17 / 304 (5.59%)	21 / 304 (6.91%)
occurrences (all)	27	22	25
Stridor			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Tonsillar hypertrophy			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Wheezing			
subjects affected / exposed	2 / 304 (0.66%)	4 / 304 (1.32%)	4 / 304 (1.32%)
occurrences (all)	2	4	4
Psychiatric disorders			
Aggression			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	2 / 304 (0.66%)	2 / 304 (0.66%)	0 / 304 (0.00%)
occurrences (all)	2	3	0
Irritability			
subjects affected / exposed	181 / 304 (59.54%)	142 / 304 (46.71%)	150 / 304 (49.34%)
occurrences (all)	185	142	152

Middle insomnia			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Investigations			
Bacterial test negative			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Blood iron decreased			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Accidental exposure to product by child			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Arthropod bite			
subjects affected / exposed	1 / 304 (0.33%)	2 / 304 (0.66%)	1 / 304 (0.33%)
occurrences (all)	1	2	1
Arthropod sting			
subjects affected / exposed	2 / 304 (0.66%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	2	0	0
Burns second degree			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Concussion			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	4 / 304 (1.32%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	4	1	0
Corneal abrasion			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Excoriation			

subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Head injury			
subjects affected / exposed	2 / 304 (0.66%)	2 / 304 (0.66%)	2 / 304 (0.66%)
occurrences (all)	3	2	5
Laceration			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Lip injury			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Mouth injury			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Muscle strain			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Tongue injury			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Wound			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Laryngomalacia			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			

Dizziness			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	0	0	0
Drooling			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Lethargy			
subjects affected / exposed	1 / 304 (0.33%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	2	1	0
Somnolence			
subjects affected / exposed	133 / 304 (43.75%)	106 / 304 (34.87%)	113 / 304 (37.17%)
occurrences (all)	133	106	114
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	1 / 304 (0.33%)
occurrences (all)	0	1	1
Iron deficiency anaemia			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Leukocytosis			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Lymphadenopathy			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	1	0	1
Ear and labyrinth disorders			
Auricular pseudocyst			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	0	0	0
Cerumen impaction			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	2 / 304 (0.66%)
occurrences (all)	0	1	2
Ear pain			
subjects affected / exposed	1 / 304 (0.33%)	1 / 304 (0.33%)	3 / 304 (0.99%)
occurrences (all)	1	1	3
Eustachian tube dysfunction			

subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Tympanic membrane perforation			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	9 / 304 (2.96%)	3 / 304 (0.99%)	0 / 304 (0.00%)
occurrences (all)	9	3	0
Dark circles under eyes			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Eye allergy			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	2	0
Eye swelling			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	2	0
Lacrimation increased			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Abdominal distension			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Aphthous stomatitis			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Bowel movement irregularity			

subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	3 / 304 (0.99%)	1 / 304 (0.33%)	4 / 304 (1.32%)
occurrences (all)	3	1	5
Diarrhoea			
subjects affected / exposed	25 / 304 (8.22%)	24 / 304 (7.89%)	19 / 304 (6.25%)
occurrences (all)	29	29	21
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Dysphagia			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Enteritis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Faeces discoloured			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	2 / 304 (0.66%)	1 / 304 (0.33%)	2 / 304 (0.66%)
occurrences (all)	3	1	3
Gastritis			
subjects affected / exposed	1 / 304 (0.33%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	1	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Proctalgia			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Stomatitis			

subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Teething			
subjects affected / exposed	35 / 304 (11.51%)	35 / 304 (11.51%)	37 / 304 (12.17%)
occurrences (all)	40	41	47
Tongue disorder			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Tooth discolouration			
subjects affected / exposed	1 / 304 (0.33%)	2 / 304 (0.66%)	1 / 304 (0.33%)
occurrences (all)	1	2	2
Vomiting			
subjects affected / exposed	13 / 304 (4.28%)	11 / 304 (3.62%)	13 / 304 (4.28%)
occurrences (all)	15	13	14
Skin and subcutaneous tissue disorders			
Blister			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	1	0	1
Dermatitis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Dermatitis atopic			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Eczema			
subjects affected / exposed	1 / 304 (0.33%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	1	1	0
Erythema			
subjects affected / exposed	46 / 304 (15.13%)	48 / 304 (15.79%)	43 / 304 (14.14%)
occurrences (all)	46	49	43
Hyperhidrosis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	2 / 304 (0.66%)
occurrences (all)	0	0	2

Petechiae			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Rash macular			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Seborrhoea			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Skin discolouration			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Ketonuria			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Knee deformity			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	1	0	1
Musculoskeletal pain			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	2 / 304 (0.66%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	2	0	1
Infections and infestations			

Abscess			
subjects affected / exposed	1 / 304 (0.33%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	1	1	0
Acarodermatitis			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Acute sinusitis			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	1 / 304 (0.33%)
occurrences (all)	0	1	1
Acute tonsillitis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Bacteraemia			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Body tinea			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Bronchiolitis			
subjects affected / exposed	3 / 304 (0.99%)	1 / 304 (0.33%)	2 / 304 (0.66%)
occurrences (all)	3	1	2
Bronchitis			
subjects affected / exposed	2 / 304 (0.66%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	2	0	1
Bronchitis viral			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Candidiasis			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Cellulitis			
subjects affected / exposed	0 / 304 (0.00%)	2 / 304 (0.66%)	1 / 304 (0.33%)
occurrences (all)	0	2	1
Conjunctivitis infective			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1

Croup infectious			
subjects affected / exposed	4 / 304 (1.32%)	3 / 304 (0.99%)	6 / 304 (1.97%)
occurrences (all)	5	3	6
Ear infection			
subjects affected / exposed	3 / 304 (0.99%)	1 / 304 (0.33%)	1 / 304 (0.33%)
occurrences (all)	3	1	1
Enterovirus infection			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Fungal infection			
subjects affected / exposed	2 / 304 (0.66%)	2 / 304 (0.66%)	0 / 304 (0.00%)
occurrences (all)	2	2	0
Gastroenteritis			
subjects affected / exposed	2 / 304 (0.66%)	5 / 304 (1.64%)	2 / 304 (0.66%)
occurrences (all)	2	5	2
Gastroenteritis viral			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	2 / 304 (0.66%)
occurrences (all)	0	1	2
Gingivitis			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	0	0	0
Herpangina			
subjects affected / exposed	2 / 304 (0.66%)	1 / 304 (0.33%)	1 / 304 (0.33%)
occurrences (all)	2	1	1
Hordeolum			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Impetigo			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Infected bites			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	0	0	0

Influenza			
subjects affected / exposed	1 / 304 (0.33%)	3 / 304 (0.99%)	2 / 304 (0.66%)
occurrences (all)	1	3	2
Lower respiratory tract infection			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	0	0	0
Molluscum contagiosum			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	10 / 304 (3.29%)	8 / 304 (2.63%)	13 / 304 (4.28%)
occurrences (all)	11	9	14
Oral candidiasis			
subjects affected / exposed	3 / 304 (0.99%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	3	0	0
Oral herpes			
subjects affected / exposed	2 / 304 (0.66%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	2	0	1
Otitis externa			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Otitis media			
subjects affected / exposed	25 / 304 (8.22%)	25 / 304 (8.22%)	29 / 304 (9.54%)
occurrences (all)	25	26	31
Otitis media acute			
subjects affected / exposed	9 / 304 (2.96%)	10 / 304 (3.29%)	8 / 304 (2.63%)
occurrences (all)	10	13	8
Otitis media chronic			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Paronychia			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Pharyngitis			
subjects affected / exposed	12 / 304 (3.95%)	7 / 304 (2.30%)	10 / 304 (3.29%)
occurrences (all)	12	7	10

Pharyngitis streptococcal			
subjects affected / exposed	1 / 304 (0.33%)	4 / 304 (1.32%)	1 / 304 (0.33%)
occurrences (all)	1	4	1
Pneumonia			
subjects affected / exposed	3 / 304 (0.99%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	3	0	0
Pneumonia bacterial			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Respiratory syncytial virus bronchitis			
subjects affected / exposed	2 / 304 (0.66%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	2	1	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	7 / 304 (2.30%)	4 / 304 (1.32%)	6 / 304 (1.97%)
occurrences (all)	7	5	8
Sinusitis			
subjects affected / exposed	3 / 304 (0.99%)	5 / 304 (1.64%)	4 / 304 (1.32%)
occurrences (all)	3	5	5
Skin infection			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Staphylococcal infection			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Streptococcal infection			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	0	1	0
Subcutaneous abscess			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 304 (0.00%)	2 / 304 (0.66%)	1 / 304 (0.33%)
occurrences (all)	0	2	1

Upper respiratory tract infection			
subjects affected / exposed	40 / 304 (13.16%)	22 / 304 (7.24%)	39 / 304 (12.83%)
occurrences (all)	40	25	40
Urinary tract infection			
subjects affected / exposed	0 / 304 (0.00%)	1 / 304 (0.33%)	1 / 304 (0.33%)
occurrences (all)	0	1	1
Viral infection			
subjects affected / exposed	7 / 304 (2.30%)	8 / 304 (2.63%)	9 / 304 (2.96%)
occurrences (all)	7	8	9
Viral pharyngitis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Viral rash			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 304 (0.33%)	1 / 304 (0.33%)	0 / 304 (0.00%)
occurrences (all)	1	1	0
Vulvovaginitis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	111 / 304 (36.51%)	77 / 304 (25.33%)	110 / 304 (36.18%)
occurrences (all)	112	78	111
Dehydration			
subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0
Feeding disorder of infancy or early childhood			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	0	0	0
Lactose intolerance			
subjects affected / exposed	0 / 304 (0.00%)	0 / 304 (0.00%)	1 / 304 (0.33%)
occurrences (all)	0	0	1
Polydipsia			

subjects affected / exposed	1 / 304 (0.33%)	0 / 304 (0.00%)	0 / 304 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	MMR-II Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	221 / 308 (71.75%)		
Vascular disorders			
Pallor			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Surgical and medical procedures			
Sinus operation			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Crying			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Discomfort			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Hyperpyrexia			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Influenza like illness			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences (all)	1		
Injection site bruising			
subjects affected / exposed	2 / 308 (0.65%)		
occurrences (all)	2		
Injection site erythema			
subjects affected / exposed	2 / 308 (0.65%)		
occurrences (all)	2		
Injection site induration			

subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Injection site mass			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences (all)	1		
Injection site reaction			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Injection site swelling			
subjects affected / exposed	2 / 308 (0.65%)		
occurrences (all)	2		
Local swelling			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences (all)	1		
Pain			
subjects affected / exposed	68 / 308 (22.08%)		
occurrences (all)	69		
Pyrexia			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Swelling			
subjects affected / exposed	15 / 308 (4.87%)		
occurrences (all)	15		
Vessel puncture site bruise			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	2 / 308 (0.65%)		
occurrences (all)	2		
Milk allergy			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences (all)	1		

Multiple allergies subjects affected / exposed occurrences (all)	0 / 308 (0.00%) 0		
Seasonal allergy subjects affected / exposed occurrences (all)	1 / 308 (0.32%) 1		
Reproductive system and breast disorders			
Genital cyst subjects affected / exposed occurrences (all)	0 / 308 (0.00%) 0		
Gynaecomastia subjects affected / exposed occurrences (all)	0 / 308 (0.00%) 0		
Penile adhesion subjects affected / exposed occurrences (all)	0 / 308 (0.00%) 0		
Vaginal discharge subjects affected / exposed occurrences (all)	0 / 308 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders			
Adenoidal hypertrophy subjects affected / exposed occurrences (all)	0 / 308 (0.00%) 0		
Asthma subjects affected / exposed occurrences (all)	0 / 308 (0.00%) 0		
Bronchial hyperreactivity subjects affected / exposed occurrences (all)	4 / 308 (1.30%) 4		
Cough subjects affected / exposed occurrences (all)	19 / 308 (6.17%) 19		
Dyspnoea subjects affected / exposed occurrences (all)	0 / 308 (0.00%) 0		
Epistaxis			

subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Increased upper airway secretion			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Nasal congestion			
subjects affected / exposed	10 / 308 (3.25%)		
occurrences (all)	11		
Nasal disorder			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences (all)	1		
Oropharyngeal pain			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Respiratory disorder			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Rhinitis allergic			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences (all)	1		
Rhinorrhoea			
subjects affected / exposed	13 / 308 (4.22%)		
occurrences (all)	13		
Stridor			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Tonsillar hypertrophy			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Wheezing			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences (all)	1		
Psychiatric disorders			
Aggression			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		

Insomnia			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Irritability			
subjects affected / exposed	153 / 308 (49.68%)		
occurrences (all)	154		
Middle insomnia			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Investigations			
Bacterial test negative			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Blood iron decreased			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences (all)	1		
Cardiac murmur			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Accidental exposure to product by child			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Arthropod bite			
subjects affected / exposed	2 / 308 (0.65%)		
occurrences (all)	2		
Arthropod sting			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Burns second degree			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Concussion			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences (all)	1		
Contusion			

subjects affected / exposed	1 / 308 (0.32%)		
occurrences (all)	1		
Corneal abrasion			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Excoriation			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Fall			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Head injury			
subjects affected / exposed	5 / 308 (1.62%)		
occurrences (all)	5		
Laceration			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences (all)	1		
Lip injury			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Mouth injury			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Muscle strain			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences (all)	1		
Thermal burn			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences (all)	1		
Tongue injury			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Wound			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences (all)	1		
Congenital, familial and genetic			

disorders Laryngomalacia subjects affected / exposed occurrences (all)	 1 / 308 (0.32%) 1		
Nervous system disorders Dizziness subjects affected / exposed occurrences (all) Drooling subjects affected / exposed occurrences (all) Lethargy subjects affected / exposed occurrences (all) Somnolence subjects affected / exposed occurrences (all)	 1 / 308 (0.32%) 1 0 / 308 (0.00%) 0 1 / 308 (0.32%) 1 109 / 308 (35.39%) 110		
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all) Iron deficiency anaemia subjects affected / exposed occurrences (all) Leukocytosis subjects affected / exposed occurrences (all) Lymphadenopathy subjects affected / exposed occurrences (all)	 2 / 308 (0.65%) 2 1 / 308 (0.32%) 1 1 / 308 (0.32%) 1 2 / 308 (0.65%) 2		
Ear and labyrinth disorders Auricular pseudocyst subjects affected / exposed occurrences (all) Cerumen impaction subjects affected / exposed occurrences (all)	 1 / 308 (0.32%) 1 2 / 308 (0.65%) 2		

Ear pain			
subjects affected / exposed	2 / 308 (0.65%)		
occurrences (all)	2		
Eustachian tube dysfunction			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Tympanic membrane perforation			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Eye disorders			
Conjunctivitis			
subjects affected / exposed	4 / 308 (1.30%)		
occurrences (all)	4		
Dark circles under eyes			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Eye allergy			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Eye swelling			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Lacrimation increased			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences (all)	1		
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Abdominal distension			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Abdominal pain upper			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Aphthous stomatitis			

subjects affected / exposed	0 / 308 (0.00%)			
occurrences (all)	0			
Bowel movement irregularity				
subjects affected / exposed	1 / 308 (0.32%)			
occurrences (all)	1			
Colitis				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences (all)	0			
Constipation				
subjects affected / exposed	3 / 308 (0.97%)			
occurrences (all)	3			
Diarrhoea				
subjects affected / exposed	21 / 308 (6.82%)			
occurrences (all)	22			
Diarrhoea haemorrhagic				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences (all)	0			
Dysphagia				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences (all)	0			
Enteritis				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences (all)	0			
Faeces discoloured				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences (all)	0			
Flatulence				
subjects affected / exposed	2 / 308 (0.65%)			
occurrences (all)	2			
Gastritis				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences (all)	0			
Gastrooesophageal reflux disease				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences (all)	0			
Proctalgia				

subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Stomatitis			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Teething			
subjects affected / exposed	35 / 308 (11.36%)		
occurrences (all)	40		
Tongue disorder			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Tooth discolouration			
subjects affected / exposed	2 / 308 (0.65%)		
occurrences (all)	7		
Vomiting			
subjects affected / exposed	12 / 308 (3.90%)		
occurrences (all)	13		
Skin and subcutaneous tissue disorders			
Blister			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Dermatitis			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Dermatitis atopic			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences (all)	1		
Dermatitis diaper			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences (all)	1		
Eczema			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences (all)	1		
Erythema			
subjects affected / exposed	49 / 308 (15.91%)		
occurrences (all)	49		

Hyperhidrosis subjects affected / exposed occurrences (all)	0 / 308 (0.00%) 0		
Petechiae subjects affected / exposed occurrences (all)	0 / 308 (0.00%) 0		
Pruritus subjects affected / exposed occurrences (all)	0 / 308 (0.00%) 0		
Rash subjects affected / exposed occurrences (all)	0 / 308 (0.00%) 0		
Rash macular subjects affected / exposed occurrences (all)	0 / 308 (0.00%) 0		
Seborrhoea subjects affected / exposed occurrences (all)	0 / 308 (0.00%) 0		
Seborrhoeic dermatitis subjects affected / exposed occurrences (all)	0 / 308 (0.00%) 0		
Skin discolouration subjects affected / exposed occurrences (all)	0 / 308 (0.00%) 0		
Renal and urinary disorders Ketonuria subjects affected / exposed occurrences (all)	0 / 308 (0.00%) 0		
Musculoskeletal and connective tissue disorders Knee deformity subjects affected / exposed occurrences (all)	0 / 308 (0.00%) 0		
Musculoskeletal pain subjects affected / exposed occurrences (all)	0 / 308 (0.00%) 0		
Pain in extremity			

subjects affected / exposed	1 / 308 (0.32%)		
occurrences (all)	1		
Infections and infestations			
Abscess			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences (all)	1		
Acarodermatitis			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Acute sinusitis			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Acute tonsillitis			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Bacteraemia			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Body tinea			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Bronchiolitis			
subjects affected / exposed	5 / 308 (1.62%)		
occurrences (all)	5		
Bronchitis			
subjects affected / exposed	3 / 308 (0.97%)		
occurrences (all)	3		
Bronchitis viral			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		
Candidiasis			
subjects affected / exposed	2 / 308 (0.65%)		
occurrences (all)	2		
Cellulitis			
subjects affected / exposed	1 / 308 (0.32%)		
occurrences (all)	1		

Conjunctivitis infective				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences (all)	0			
Croup infectious				
subjects affected / exposed	3 / 308 (0.97%)			
occurrences (all)	3			
Ear infection				
subjects affected / exposed	3 / 308 (0.97%)			
occurrences (all)	3			
Enterovirus infection				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences (all)	0			
Fungal infection				
subjects affected / exposed	1 / 308 (0.32%)			
occurrences (all)	1			
Gastroenteritis				
subjects affected / exposed	5 / 308 (1.62%)			
occurrences (all)	5			
Gastroenteritis viral				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences (all)	0			
Gingivitis				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences (all)	0			
Hand-foot-and-mouth disease				
subjects affected / exposed	1 / 308 (0.32%)			
occurrences (all)	1			
Herpangina				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences (all)	0			
Hordeolum				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences (all)	0			
Impetigo				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences (all)	0			

Infected bites				
subjects affected / exposed	1 / 308 (0.32%)			
occurrences (all)	1			
Influenza				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences (all)	0			
Lower respiratory tract infection				
subjects affected / exposed	1 / 308 (0.32%)			
occurrences (all)	1			
Molluscum contagiosum				
subjects affected / exposed	1 / 308 (0.32%)			
occurrences (all)	1			
Nasopharyngitis				
subjects affected / exposed	9 / 308 (2.92%)			
occurrences (all)	9			
Oral candidiasis				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences (all)	0			
Oral herpes				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences (all)	0			
Otitis externa				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences (all)	0			
Otitis media				
subjects affected / exposed	24 / 308 (7.79%)			
occurrences (all)	26			
Otitis media acute				
subjects affected / exposed	5 / 308 (1.62%)			
occurrences (all)	5			
Otitis media chronic				
subjects affected / exposed	1 / 308 (0.32%)			
occurrences (all)	2			
Paronychia				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences (all)	0			

Pharyngitis				
subjects affected / exposed	6 / 308 (1.95%)			
occurrences (all)	6			
Pharyngitis streptococcal				
subjects affected / exposed	3 / 308 (0.97%)			
occurrences (all)	3			
Pneumonia				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences (all)	0			
Pneumonia bacterial				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences (all)	0			
Respiratory syncytial virus bronchitis				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences (all)	0			
Respiratory syncytial virus infection				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences (all)	0			
Rhinitis				
subjects affected / exposed	4 / 308 (1.30%)			
occurrences (all)	4			
Sinusitis				
subjects affected / exposed	3 / 308 (0.97%)			
occurrences (all)	3			
Skin infection				
subjects affected / exposed	1 / 308 (0.32%)			
occurrences (all)	1			
Staphylococcal infection				
subjects affected / exposed	1 / 308 (0.32%)			
occurrences (all)	1			
Streptococcal infection				
subjects affected / exposed	0 / 308 (0.00%)			
occurrences (all)	0			
Subcutaneous abscess				
subjects affected / exposed	1 / 308 (0.32%)			
occurrences (all)	1			

Tonsillitis subjects affected / exposed occurrences (all)	0 / 308 (0.00%) 0		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	43 / 308 (13.96%) 46		
Urinary tract infection subjects affected / exposed occurrences (all)	1 / 308 (0.32%) 1		
Viral infection subjects affected / exposed occurrences (all)	11 / 308 (3.57%) 11		
Viral pharyngitis subjects affected / exposed occurrences (all)	0 / 308 (0.00%) 0		
Viral rash subjects affected / exposed occurrences (all)	0 / 308 (0.00%) 0		
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 308 (0.00%) 0		
Vulvovaginitis subjects affected / exposed occurrences (all)	1 / 308 (0.32%) 1		
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	95 / 308 (30.84%) 96		
Dehydration subjects affected / exposed occurrences (all)	0 / 308 (0.00%) 0		
Feeding disorder of infancy or early childhood subjects affected / exposed occurrences (all)	1 / 308 (0.32%) 1		
Lactose intolerance			

subjects affected / exposed	1 / 308 (0.32%)		
occurrences (all)	1		
Polydipsia			
subjects affected / exposed	0 / 308 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 June 2010	•Update Sponsor contact details for reporting SAEs and for emergency unblinding. •Clarify the timeframe to which medications, treatments and/or vaccinations are to be recorded in the eCRF. •Clarify the that the second dose of Havrix is not a part of the study procedures, but is recorded in the eCRF.
29 April 2011	Clarify/require the collection of any subsequent MMR vaccinations through visit 5. Change/update the interim analysis from a yearly persistence analysis to a 2 year analysis.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported