



## Clinical trial results:

**Blinded, randomized, controlled, multicenter study to evaluate the clinical efficacy against varicella disease of GlaxoSmithKline Biologicals' live attenuated varicella vaccine (Varilrix) given on a one-dose schedule and of GlaxoSmithKline Biologicals' combined measles-mumps-rubella-varicella vaccine (Priorix™-Tetra) given on a two-dose schedule in healthy children during the second year of life**

### Summary

EudraCT number	2004-002676-41
Trial protocol	SE LT SK CZ IT
Global end of trial date	15 December 2016

### Results information

Result version number	v1
This version publication date	01 July 2017
First version publication date	01 July 2017

### Trial information

#### Trial identification

Sponsor protocol code	100388
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#### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00226499
WHO universal trial number (UTN)	-
Other trial identifiers	EXT FU Y2: 104105, EXT FU Y1: 103494, EXT FU Y4-Y6-Y8-Y10: 104106

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 2089904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 44 2089904466, 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	15 December 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 December 2016
Global end of trial reached?	Yes
Global end of trial date	15 December 2016
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

- To demonstrate the efficacy of one dose of Varilrix in preventing confirmed varicella cases\* over at least two years after vaccination.

OR/AND

- To demonstrate the efficacy of two doses of Priorix-Tetra in preventing confirmed varicella cases\* over at least two years after vaccination.

\* Varicella cases were defined per protocol and according to Center for Disease Control (CDC, 2002) as an illness with an acute onset of diffuse, generalized maculopapulovesicular rash (i.e. spots, papules and/or vesicles) WITHOUT OTHER APPARENT CAUSE.

Protection of trial subjects:

The subjects were observed closely for at least 30 minutes following the administration of vaccines, with appropriate medical treatment readily available in case of a rare anaphylactic reaction.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 September 2005
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Czech Republic: 1286
Country: Number of subjects enrolled	Greece: 307
Country: Number of subjects enrolled	Italy: 283
Country: Number of subjects enrolled	Lithuania: 647
Country: Number of subjects enrolled	Norway: 204
Country: Number of subjects enrolled	Poland: 946
Country: Number of subjects enrolled	Romania: 335
Country: Number of subjects enrolled	Russian Federation: 1000
Country: Number of subjects enrolled	Slovakia: 491
Country: Number of subjects enrolled	Sweden: 304
Worldwide total number of subjects	5803
EEA total number of subjects	4803

Notes:

<b>Subjects enrolled per age group</b>	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	5801
Children (2-11 years)	2
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

During the screening the following steps occurred: check for inclusion/exclusion criteria, contraindications/precautions, medical history of the subjects and signing informed consent forms.

### Period 1

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

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	MMRV Group

Arm description:

Subjects in this group received 2 doses of Priorix-Tetra vaccine, administered subcutaneously in the deltoid region of the left arm, one at Day 0 (Visit 1) and the other at Day 42 (Visit 2).

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

Dosage and administration details:

2 doses administered subcutaneously, one at Day 0 and the other at Day 42 to subjects in MMRV Group.

<b>Arm title</b>	OKAH Group
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Arm description:

Subjects in this group received 1 dose of Priorix at Day 0 (Visit 1) and 1 dose of Varilrix at Day 42 (Visit 2). Both vaccines were administered subcutaneously in the deltoid region of the left arm.

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

Dosage and administration details:

1 dose administered subcutaneously at Day 42 to subjects in OKAH Group.

Investigational medicinal product name	Priorix™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

2 doses administered subcutaneously, one at Day 0 and the other at Day 42 to subjects in MMR Group and one dose administered subcutaneously at Day 0 to subjects in OKAH Group.

<b>Arm title</b>	MMR Group
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**Arm description:**

Subjects in this group received 2 doses of Priorix, administered subcutaneously in the deltoid region of the left arm, one at Day 0 (Visit 1) and the other at Day 42 (Visit 2).

Arm type	Active comparator
Investigational medicinal product name	Priorix™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Subcutaneous use

**Dosage and administration details:**

2 doses administered subcutaneously, one at Day 0 and the other at Day 42 to subjects in MMR Group and one dose administered subcutaneously at Day 0 to subjects in OKAH Group.

<b>Number of subjects in period 1</b>	MMRV Group	OKAH Group	MMR Group
Started	2489	2487	827
Completed	1415	1415	468
Not completed	1074	1072	359
Others	1064	1066	356
Adverse event, non-fatal	10	6	3

## Baseline characteristics

### Reporting groups

Reporting group title	MMRV Group
Reporting group description:	
Subjects in this group received 2 doses of Priorix-Tetra vaccine, administered subcutaneously in the deltoid region of the left arm, one at Day 0 (Visit 1) and the other at Day 42 (Visit 2).	
Reporting group title	OKAH Group
Reporting group description:	
Subjects in this group received 1 dose of Priorix at Day 0 (Visit 1) and 1 dose of Varilrix at Day 42 (Visit 2). Both vaccines were administered subcutaneously in the deltoid region of the left arm.	
Reporting group title	MMR Group
Reporting group description:	
Subjects in this group received 2 doses of Priorix, administered subcutaneously in the deltoid region of the left arm, one at Day 0 (Visit 1) and the other at Day 42 (Visit 2).	

Reporting group values	MMRV Group	OKAH Group	MMR Group
Number of subjects	2489	2487	827
Age categorical			
Units: Subjects			

Age continuous			
Units: months			
arithmetic mean	14.3	14.2	14.2
standard deviation	± 2.5	± 2.5	± 2.5
Gender categorical			
Units: Subjects			
Female	1154	1223	401
Male	1335	1264	426
Race/Ethnicity, Customized			
Units: Subjects			
Race American hispanic	1	5	2
Race Arabic/north african	24	7	3
Race Black	9	9	1
Race East/south east asian	8	7	1
Race Japanese	1	0	0
Race Other	13	11	1
Race South asian	3	2	1
Race White/caucasian	2430	2446	818

Reporting group values	Total		
Number of subjects	5803		
Age categorical			
Units: Subjects			

Age continuous			
Units: months			
arithmetic mean			
standard deviation	-		

Gender categorical			
Units: Subjects			
Female	2778		
Male	3025		
Race/Ethnicity, Customized			
Units: Subjects			
Race American hispanic	8		
Race Arabic/north african	34		
Race Black	19		
Race East/south east asian	16		
Race Japanese	1		
Race Other	25		
Race South asian	6		
Race White/caucasian	5694		

## End points

### End points reporting groups

Reporting group title	MMRV Group
Reporting group description: Subjects in this group received 2 doses of Priorix-Tetra vaccine, administered subcutaneously in the deltoid region of the left arm, one at Day 0 (Visit 1) and the other at Day 42 (Visit 2).	
Reporting group title	OKAH Group
Reporting group description: Subjects in this group received 1 dose of Priorix at Day 0 (Visit 1) and 1 dose of Varilrix at Day 42 (Visit 2). Both vaccines were administered subcutaneously in the deltoid region of the left arm.	
Reporting group title	MMR Group
Reporting group description: Subjects in this group received 2 doses of Priorix, administered subcutaneously in the deltoid region of the left arm, one at Day 0 (Visit 1) and the other at Day 42 (Visit 2).	

### Primary: Phase A: Number of subjects with confirmed varicella case

End point title	Phase A: Number of subjects with confirmed varicella case <sup>[1]</sup>
End point description: Confirmed varicella case = A case that met the clinical case definition at least in the opinion of the investigator and was confirmed by laboratory test [PCR (+)] OR a case that met the clinical definition confirmed by the Independent Data Monitoring Committee (IDMC) and was epidemiologically linked [Epi (+)] to a valid index case.	
End point type	Primary
End point timeframe: From 42 days post dose 2 until the end of Phase A	

#### 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: 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.

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2279	2263	743	
Units: Participants				
Participants	37	243	201	

### Statistical analyses

No statistical analyses for this end point

### Primary: Phase A: Vaccine efficacy in subjects with confirmed varicella case

End point title	Phase A: Vaccine efficacy in subjects with confirmed varicella case <sup>[2][3]</sup>
End point description: Vaccine Efficacy (VE) was defined as efficacy of one dose of Varilrix or two doses of Priorix-Tetra in preventing confirmed varicella cases. Confirmed varicella case = A case that met the clinical case definition at least in the opinion of the investigator and was confirmed by laboratory test [PCR (+)] OR a	



case that met the clinical definition confirmed by the Independent Data Monitoring Committee (IDMC) and was epidemiologically linked [Epi (+)] to a valid index case.

End point type	Primary
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End point timeframe:

42 days post dose 2 until the end of Phase A

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: 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.

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The results in this end point were tabulated as vaccine efficacy of Varilrix when compared to Priorix and vaccine efficacy of Priorix-Tetra when compared to Priorix. This endpoint therefore presents the results for groups applicable for this analysis (i.e., MMRV & OKAH Groups).

End point values	MMRV Group	OKAH Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2279	2263		
Units: Percentage				
number (confidence interval 97.5%)	94.943 (92.446 to 96.615)	65.428 (57.182 to 72.086)		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase A: Number of subjects with moderate or severe confirmed varicella case

End point title	Phase A: Number of subjects with moderate or severe confirmed varicella case
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End point description:

Confirmed varicella case = A case that met the clinical case definition at least in the opinion of the investigator and was confirmed by laboratory test [PCR (+)] OR a case that met the clinical definition confirmed by the IDMC and was epidemiologically linked [Epi (+)] to a valid index case. Moderately severe disease = 8-15 points; severe disease:  $\geq 16$  points (scored by IDMC using the modified Vázquez scale).

End point type	Secondary
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End point timeframe:

From 42 days post dose 2 until the end of Phase A

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2279	2263	743	
Units: Participants				
Participants	2	37	117	

## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase A: Vaccine efficacy in subjects with moderate or severe confirmed varicella case

End point title	Phase A: Vaccine efficacy in subjects with moderate or severe confirmed varicella case <sup>[4]</sup>
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End point description:

VE was defined as efficacy of one dose of Varilrix or two doses of Priorix-Tetra in preventing moderate or severe confirmed varicella cases. Confirmed varicella case = A case that met the clinical case definition at least in the opinion of the investigator and was confirmed by laboratory test [PCR (+)] OR a case that met the clinical definition confirmed by the IDMC and was epidemiologically linked [Epi (+)] to a valid index case.

Moderately severe disease = 8-15 points; severe disease:  $\geq 16$  points (scored by IDMC using the modified Vázquez scale).

End point type	Secondary
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End point timeframe:

42 days post dose 2 until the end of Phase A

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The results in this end point were tabulated as vaccine efficacy of Varilrix when compared to Priorix and vaccine efficacy of Priorix-Tetra when compared to Priorix. This endpoint therefore presents the results for groups applicable for this analysis (i.e., MMRV & OKAH Groups).

End point values	MMRV Group	OKAH Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2279	2263		
Units: Percentage				
number (confidence interval 95%)	99.498 (97.522 to 99.898)	90.741 (85.866 to 93.934)		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase A: Number of subjects with probable or confirmed varicella case

End point title	Phase A: Number of subjects with probable or confirmed varicella case
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End point description:

Probable or confirmed varicella = An illness with acute onset of diffuse, generalized maculopapulovesicular rash (i.e. spots, papules and/or vesicles) without other apparent cause.

End point type	Secondary
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End point timeframe:

From 42 days post dose 2 until the end of Phase A

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2279	2263	743	
Units: Participants				
Participants	57	260	209	

## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase A: Vaccine efficacy in subjects with probable or confirmed varicella case

End point title	Phase A: Vaccine efficacy in subjects with probable or confirmed varicella case <sup>[5]</sup>
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End point description:

VE was defined as efficacy of one dose of Varilrix or two doses of Priorix-Tetra in preventing probable or confirmed varicella cases. Probable or confirmed varicella = An illness with acute onset of diffuse, generalized maculopapulovesicular rash (i.e. spots, papules and/or vesicles) without other apparent cause.

End point type	Secondary
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End point timeframe:

42 days post dose 2 until the end of Phase A

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The results in this end point were tabulated as vaccine efficacy of Varilrix when compared to Priorix and vaccine efficacy of Priorix-Tetra when compared to Priorix. This endpoint therefore presents the results for groups applicable for this analysis (i.e., MMRV & OKAH Groups).

End point values	MMRV Group	OKAH Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2279	2263		
Units: Percentage				
number (confidence interval 95%)	92.487 (89.927 to 94.396)	64.585 (57.503 to 70.486)		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase A: Immune response to varicella vaccine with respect to anti-Varicella Zoster Virus (anti-VZV) antibody concentrations

End point title	Phase A: Immune response to varicella vaccine with respect to anti-Varicella Zoster Virus (anti-VZV) antibody concentrations
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End point description:

Anti-VZV antibody concentrations are presented as Geometric Mean Concentrations (GMCs), expressed in milliinternational units per milliliter (mIU/mL).

End point type	Secondary
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End point timeframe:

At Day 0, Day 42, Day 84, Year 1 and Year 2 time points

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2245	2245	742	
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-VZV, Day 0 (N=2245;2245;742)	12.8 (12.6 to 12.9)	12.7 (12.6 to 12.8)	12.6 (12.5 to 12.8)	
Anti-VZV, Day 42 (N=690;697;231)	116.1 (108.3 to 124.5)	13.5 (13 to 14.1)	13.1 (12.5 to 13.9)	
Anti-VZV, Day 84 (N=2241;2234;740)	1833.3 (1767.8 to 1901.3)	98.1 (94.2 to 102.3)	14.7 (13.9 to 15.6)	
Anti-VZV, Year 1 (N=2066;2053;673)	365.1 (349 to 381.9)	145.2 (137 to 153.8)	20.3 (18.2 to 22.5)	
Anti-VZV, Year 2 (N=1924;1916;635)	414.6 (392.1 to 438.5)	170.6 (158.1 to 184.1)	36.9 (31.6 to 43.1)	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase A: Number of subjects with seroconversion/seroresponse to VZV

End point title	Phase A: Number of subjects with seroconversion/seroresponse to VZV
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End point description:

Seronegative (S-) = Subjects with antibody concentration less than (<) 25 mIU/mL prior to vaccination.  
Seropositive (S+) = Subjects with antibody concentration greater than or equal to (≥) 25 mIU/mL prior to vaccination. Seroconversion was defined as the appearance of antibodies (i.e. titer greater than or equal to the cut-off value) in the serum of subjects seronegative before vaccination.

End point type	Secondary
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End point timeframe:

At Day 0, Day 42, Day 84, Year 1 and Year 2 time points

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2245	2245	742	
Units: Participants				
Anti-VZV, Day 0 (N=2245;2245;742)	26	24	4	
Anti-VZV, Day 42 (N=690;697;231)	661	21	6	
Anti-VZV, Day 84 (N=2241;2234;740)	2236	2123	40	
Anti-VZV, Year 1 (N=2066;2053;673)	2056	1968	91	
Anti-VZV, Year 2 (N=1924;1916;635)	1913	1776	170	

## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase A: Immune response to measles with respect to anti-measles antibody concentrations in a subset of subjects

End point title	Phase A: Immune response to measles with respect to anti-measles antibody concentrations in a subset of subjects
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End point description:

Anti-measles antibody concentrations are presented as Geometric Mean Concentrations (GMCs), expressed in milliinternational units per milliliter (mIU/mL).

End point type	Secondary
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End point timeframe:

At Day 0, Day 42, Day 84, Year 1 and Year 2 time points

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	704	713	232	
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-measles, Day 0 (N=704;713;232)	75.7 (74.6 to 76.8)	77.9 (75.6 to 80.3)	77.9 (73.9 to 82.1)	
Anti-measles, Day 42 (N=691;698;230)	3961 (3719.7 to 4217.9)	2602.7 (2429.6 to 2788.1)	2817.4 (2506.3 to 3167.1)	
Anti-measles, Day 84 (N=704;712;231)	5809.6 (5544.5 to 6087.3)	3438.1 (3210.9 to 3681.5)	3695 (3318.2 to 4114.6)	
Anti-measles, Year 1 (N=630;630;200)	4993.7 (4714.7 to 5289.2)	2856.8 (2658.6 to 3069.7)	2885.7 (2520.7 to 3303.5)	
Anti-measles, Year 2 (N=589;593;187)	4709.6 (4407.1 to 5033)	2624.5 (2423.6 to 2842.2)	2677.9 (2302.5 to 3114.5)	

## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase A: Number of subjects with seroconversion/seroresponse to measles in a subset of subjects

End point title	Phase A: Number of subjects with seroconversion/seroresponse to measles in a subset of subjects
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End point description:

Seronegative (S-) = Subjects with antibody concentration < 150 mIU/mL prior to vaccination.

Seropositive (S+) = Subjects with antibody concentration ≥ 150 mIU/mL prior to vaccination.

Seroconversion was defined as the appearance of antibodies (i.e. titer greater than or equal to the cut-off value) in the serum of subjects seronegative before vaccination.

End point type	Secondary
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End point timeframe:

At Day 0, Day 42, Day 84, Year 1 and Year 2 time points

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	704	713	232	
Units: Participants				
Anti-measles, Day 0 (N=704;713;232)	2	7	2	
Anti-measles, Day 42 (N=691;698;230)	676	682	225	
Anti-measles, Day 84 (N=704;712;231)	703	702	230	
Anti-measles, Year 1 (N=630;630;200)	628	621	198	
Anti-measles, Year 2 (N=589;593;187)	584	583	183	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase A: Immune response to mumps with respect to anti-mumps antibody concentrations in a subset of subjects

End point title	Phase A: Immune response to mumps with respect to anti-mumps antibody concentrations in a subset of subjects
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End point description:

Anti-mumps antibody concentrations are presented as Geometric Mean Concentrations (GMCs), expressed in units per milliliter (U/mL).

End point type	Secondary
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End point timeframe:

At Day 0, Day 42, Day 84, Year 1 and Year 2 time points

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	704	712	232	
Units: U/mL				
geometric mean (confidence interval 95%)				
Anti-mumps, Day 0 (N=704;712;232)	117.5 (115.4 to 119.7)	119.1 (116.2 to 122.2)	118.1 (114.4 to 122)	
Anti-mumps, Day 42 (N=667;670;225)	896.6 (827 to 972)	925 (859.4 to 995.7)	945.2 (839 to 1064.9)	

Anti-mumps, Day 84 (N=698;701;225)	1496.8 (1407.7 to 1591.7)	759.8 (705.5 to 818.3)	1547.9 (1408 to 1701.6)	
Anti-mumps, Year 1 (N=624;622;196)	1008.6 (928.8 to 1095.2)	875.9 (805.8 to 952.2)	1089.6 (944 to 1257.5)	
Anti-mumps, Year 2 (N=582;587;187)	1050.6 (957.5 to 1152.7)	882 (805.6 to 965.6)	989.4 (848.3 to 1153.9)	

## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase A: Number of subjects with seroconversion/seroresponse to mumps in a subset of subjects

End point title	Phase A: Number of subjects with seroconversion/seroresponse to mumps in a subset of subjects
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End point description:

Seronegative (S-) = Subjects with antibody concentration < 231 U/mL prior to vaccination. Seropositive (S+) = Subjects with antibody concentration ≥ 231 U/mL prior to vaccination. Seroconversion was defined as the appearance of antibodies (i.e. titer greater than or equal to the cut-off value) in the serum of subjects seronegative before vaccination.

End point type	Secondary
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End point timeframe:

At Day 0, Day 42, Day 84, Year 1 and Year 2 time points

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	704	712	232	
Units: Participants				
Anti-mumps, Day 0 (N=704;712;232)	4	6	2	
Anti-mumps, Day 42 (N=667;670;225)	584	613	208	
Anti-mumps, Day 84 (N=698;701;225)	683	608	225	
Anti-mumps, Year 1 (N=624;622;196)	569	554	182	
Anti-mumps, Year 2 (N=582;587;187)	527	520	171	

## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase A: Immune response to rubella with respect to anti-rubella antibody concentrations in a subset of subjects

End point title	Phase A: Immune response to rubella with respect to anti-rubella antibody concentrations in a subset of subjects
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End point description:

Anti-rubella antibody concentrations are presented as Geometric Mean Concentrations (GMCs), expressed in International Units per milliliter (IU/mL).

End point type	Secondary
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End point timeframe:

At Day 0, Day 42, Day 84, Year 1 and Year 2 time points

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	704	713	232	
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-rubella, Day 0 (N=704;713;232)	2.1 (2 to 2.1)	2 (2 to 2.1)	2.1 (2 to 2.2)	
Anti-rubella, Day 42 (N=692;698;230)	57.6 (54.2 to 61.2)	74 (69.9 to 78.3)	71 (64.8 to 77.8)	
Anti-rubella, Day 84 (N=704;712;231)	104.7 (99.8 to 109.8)	122.1 (116.2 to 128.2)	111.9 (103.5 to 120.9)	
Anti-rubella, Year 1 (N=630;630;200)	88.7 (83.9 to 93.8)	103.7 (97.8 to 110)	98 (88.7 to 108.3)	
Anti-rubella, Year 2 (N=589;593;187)	71.8 (67.5 to 76.4)	79.1 (74.2 to 84.3)	71.8 (64 to 80.5)	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase A: Number of subjects with a seroconversion/seroresponse to rubella in a subset of subjects

End point title	Phase A: Number of subjects with a seroconversion/seroresponse to rubella in a subset of subjects
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End point description:

Seronegative (S-) = Subjects with antibody concentration < 4 IU/mL prior to vaccination. Seropositive (S+) = Subjects with antibody concentration ≥ 4 IU/mL prior to vaccination. Seroconversion was defined as the appearance of antibodies (i.e. titer greater than or equal to the cut-off value) in the serum of subjects seronegative before vaccination.

End point type	Secondary
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End point timeframe:

At Day 0, Day 42, Day 84, Year 1 and Year 2 time points

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	704	713	232	
Units: Participants				
Anti-rubella, Day 0 (N=704;713;232)	7	5	2	
Anti-rubella, Day 42 (N=692;698;230)	688	693	230	
Anti-rubella, Day 84 (N=704;712;231)	704	710	231	
Anti-rubella, Year 1 (N=630;630;200)	630	628	200	
Anti-rubella, Year 2 (N=589;593;187)	589	590	186	



## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase A: Number of subjects with confirmed cases of herpes zoster

End point title	Phase A: Number of subjects with confirmed cases of herpes zoster
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End point description:

The number of subjects with confirmed cases of herpes zoster is reported.

End point type	Secondary
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End point timeframe:

From Day 0 until the end of Phase A (Year 2)

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	807	812	268	
Units: Participants				
Participants	0	0	0	

## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase A: Number of subjects reporting fever

End point title	Phase A: Number of subjects reporting fever
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End point description:

All fever ( $\geq 38^{\circ}\text{C}$ ) = occurrence of any fever (measured rectally) regardless of its intensity grade or relationship to vaccination. Related = fever (measured rectally) assessed by the investigator to be causally related to the study vaccination. Medical Advice = Seek for medical advice.

End point type	Secondary
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End point timeframe:

Within 43 days (Day 0-42) post-vaccination period following each dose

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	784	795	256	
Units: Participants				
All Fever, Dose 1	503	439	132	
Related Fever, Dose 1	332	240	82	
Related Fever $\geq 38^{\circ}\text{C}$ , Dose 1	332	240	82	
Related Fever $> 38.5^{\circ}\text{C}$ , Dose 1	222	147	46	
Related Fever $> 39^{\circ}\text{C}$ , Dose 1	141	90	29	
Related Fever $> 39.5^{\circ}\text{C}$ , Dose 1	71	48	13	
Related Fever $> 40^{\circ}\text{C}$ , Dose 1	22	18	5	
Fever $\geq 38^{\circ}\text{C}$ , Dose 1	503	439	132	
Fever $> 38.5^{\circ}\text{C}$ , Dose 1	359	297	84	
Fever $> 39^{\circ}\text{C}$ , Dose 1	249	191	55	
Fever $> 39.5^{\circ}\text{C}$ , Dose 1	139	100	29	
Fever $> 40^{\circ}\text{C}$ , Dose 1	49	43	15	
Fever Medical advice, Dose 1	203	177	46	
All Fever, Dose 2 (N=758;773;247)	303	313	103	
Related Fever, Dose 2 (N=758;773;247)	136	144	41	
Related Fever $\geq 38^{\circ}\text{C}$ , Dose 2 (N=758;773;247)	136	144	41	
Related Fever $> 38.5^{\circ}\text{C}$ , Dose 2 (N=758;773;247)	78	88	25	
Related Fever $> 39^{\circ}\text{C}$ , Dose 2 (N=758;773;247)	51	54	20	
Related Fever $> 39.5^{\circ}\text{C}$ , Dose 2 (N=758;773;247)	25	32	11	
Related Fever $> 40^{\circ}\text{C}$ , Dose 2 (N=758;773;247)	9	9	3	
Fever $\geq 38^{\circ}\text{C}$ , Dose 2 (N=758;773;247)	303	313	103	
Fever $> 38.5^{\circ}\text{C}$ , Dose 2 (N=758;773;247)	212	205	69	
Fever $> 39^{\circ}\text{C}$ , Dose 2 (N=758;773;247)	136	132	54	
Fever $> 39.5^{\circ}\text{C}$ , Dose 2 (N=758;773;247)	66	74	30	
Fever $> 40^{\circ}\text{C}$ , Dose 2 (N=758;773;247)	20	25	8	
Fever Medical advice, Dose 2 (N=758;773;247)	112	119	44	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase A: Number of subjects reporting fever

End point title	Phase A: Number of subjects reporting fever
End point description:	
All fever ( $\geq 38^{\circ}\text{C}$ ) = Occurrence of any fever (measured rectally) regardless of its intensity grade or relationship to vaccination. Related fever = fever (measured rectally) assessed by the investigator to be causally related to the study vaccination. Medical Advice = Seek for medical advice.	
End point type	Secondary

End point timeframe:

Within 15 days (Day 0-14) post-vaccination period following each dose

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	784	795	256	
Units: Participants				
All Fever, Dose 1	450	354	102	
Related Fever, Dose 1	328	226	69	
Related Fever $\geq 38^{\circ}\text{C}$ , Dose 1	328	226	69	
Related Fever $> 38.5^{\circ}\text{C}$ , Dose 1	216	134	36	
Related Fever $> 39^{\circ}\text{C}$ , Dose 1	135	82	23	
Related Fever $> 39.5^{\circ}\text{C}$ , Dose 1	67	42	10	
Related Fever $> 40^{\circ}\text{C}$ , Dose 1	19	15	4	
Fever $\geq 38^{\circ}\text{C}$ , Dose 1	449	349	101	
Fever $> 38.5^{\circ}\text{C}$ , Dose 1	300	213	54	
Fever $> 39^{\circ}\text{C}$ , Dose 1	196	124	34	
Fever $> 39.5^{\circ}\text{C}$ , Dose 1	101	58	16	
Fever $> 40^{\circ}\text{C}$ , Dose 1	30	21	6	
Fever Medical advice, Dose 1	140	100	26	
All Fever, Dose 2 (N=758;773;247)	189	201	55	
Related Fever, Dose 2 (N=758;773;247)	118	125	32	
Related Fever $\geq 38^{\circ}\text{C}$ , Dose 2 (N=758;773;247)	118	125	32	
Related Fever $> 38.5^{\circ}\text{C}$ , Dose 2 (N=758;773;247)	60	73	18	
Related Fever $> 39^{\circ}\text{C}$ , Dose 2 (N=758;773;247)	34	41	16	
Related Fever $> 39.5^{\circ}\text{C}$ , Dose 2 (N=758;773;247)	17	22	9	
Related Fever $> 40^{\circ}\text{C}$ , Dose 2 (N=758;773;247)	6	5	3	
Fever $\geq 38^{\circ}\text{C}$ , Dose 2 (N=758;773;247)	184	200	51	
Fever $> 38.5^{\circ}\text{C}$ , Dose 2 (N=758;773;247)	101	110	30	
Fever $> 39^{\circ}\text{C}$ , Dose 2 (N=758;773;247)	62	65	24	
Fever $> 39.5^{\circ}\text{C}$ , Dose 2 (N=758;773;247)	28	35	14	
Fever $> 40^{\circ}\text{C}$ , Dose 2 (N=758;773;247)	8	11	4	
Fever Medical Advice, Dose 2 (N=758;773;247)	43	48	13	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase A: Number of subjects reporting solicited local symptoms

End point title	Phase A: Number of subjects reporting solicited local symptoms
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End point description:

Solicited local symptoms assessed were pain, redness and swelling. Any solicited local symptom = Occurrence of any local symptom regardless of their intensity grade. Grade 3 pain = Cried when limb was moved/spontaneously painful. Grade 3 redness and swelling = greater than (>) 20 mm.

End point type	Secondary
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End point timeframe:

4 days post-vaccination period following each dose

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	782	796	256	
Units: Participants				
Any Pain, Dose 1	74	83	20	
Grade 3 Pain, Dose 1	1	2	0	
Any Redness, Dose 1	137	154	36	
Grade 3 Redness, Dose 1	3	3	0	
Any Swelling, Dose 1	38	37	6	
Grade 3 Swelling, Dose 1	3	0	0	
Any Pain, Dose 2 (N=758;774;247)	91	63	16	
Grade 3 Pain, Dose 2 (N=758;774;247)	0	1	1	
Any Redness, Dose 2 (N=758;774;247)	188	106	23	
Grade 3 Redness, Dose 2 (N=758;774;247)	26	3	0	
Any Swelling, Dose 2 (N=758;774;247)	72	31	3	
Grade 3 Swelling, Dose 2 (N=758;774;247)	4	0	0	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase A: Number of subjects reporting meningism

End point title	Phase A: Number of subjects reporting meningism
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End point description:

Any = Occurrence of meningism regardless of its intensity grade. Grade 3 meningism = Prevented normal, everyday activities. Related = Assessed by the investigator to be causally related to the study vaccination.

End point type	Secondary
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End point timeframe:

Within 43 days (Day 0-42) post-vaccination period following each dose

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	784	795	256	
Units: Participants				
Any Meningism, Dose 1	1	0	0	
Grade 3 Meningism, Dose 1	1	0	0	
Related Meningism, Dose 1	1	0	0	
Any Meningism, Dose 2 (N=758;773;247)	0	1	0	
Grade 3 Meningism, Dose 2 (N=758;773;247)	0	0	0	
Related Meningism, Dose 2 (N=758;773;247)	0	0	0	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase A: Number of subjects reporting parotitis

End point title	Phase A: Number of subjects reporting parotitis
End point description: Any = Occurrence of parotitis regardless of its intensity grade. Grade 3 parotitis = Swelling with accompanying general symptoms. Related = Assessed by the investigator to be causally related to the study.	
End point type	Secondary
End point timeframe: Within 43 days (Day 0-42) post-vaccination period following each dose	

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	784	795	256	
Units: Participants				
Any Parotitis, Dose 1	4	5	1	
Grade 3 Parotitis, Dose 1	2	1	0	
Related Parotitis, Dose 1	3	3	0	
Any Parotitis, Dose 2 (N=758;773;247)	0	2	0	
Grade 3 Parotitis, Dose 2 (N=758;773;247)	0	1	0	
Related Parotitis, Dose 2 (N=758;773;247)	0	1	0	

## Statistical analyses

No statistical analyses for this end point

**Secondary: Phase A: Number of subjects reporting rash**

End point title	Phase A: Number of subjects reporting rash
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End point description:

Any = Occurrence of rash regardless of its intensity grade. Grade 3 rash = 101-500 lesions. Grade 4 rash = > 500 lesions. Related rash = Assessed by the investigator to be causally related to the study vaccination.

End point type	Secondary
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End point timeframe:

Within 43 days (Day 0-42) post-vaccination period following each dose

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	784	795	256	
Units: Participants				
Any Local. or general., Dose 1	82	84	30	
Any Localized, Dose 1	14	15	6	
Localized Admin. site, Dose 1	0	1	0	
Localized Other site, Dose 1	14	14	6	
Any Generalized, Dose 1	68	69	24	
Generalized with fever, Dose 1	41	41	14	
Generalized Measles/Rubella, Dose 1	30	24	9	
Generalized Grade 3/4, Dose 1	9	12	7	
Generalized Grade 4, Dose 1	2	2	4	
Generalized Related, Dose 1	27	32	13	
Any Local. or general., Dose 2	42	36	9	
(N=758;773;247)				
Any Localized, Dose 2 (N=758;773;247)	5	12	4	
Localized Admin. site, Dose 2	0	2	0	
(N=758;773;247)				
Localized Other site, Dose 2	5	10	4	
(N=758;773;247)				
Any Generalized, Dose 2	37	24	5	
(N=758;773;247)				
Generalized with fever, Dose 2	9	11	4	
(N=758;773;247)				
Generalized Measles/Rubella, Dose 2	8	4	0	
(N=758;773;247)				
Generalized Grade 3/4, Dose 2	5	6	1	
(N=758;773;247)				
Generalized Grade 4, Dose 2	2	1	0	
(N=758;773;247)				
Generalized Related, Dose 2	12	6	1	
(N=758;773;247)				

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Phase A: Number of subjects with suspected sign of meningism**

**including febrile convulsions**

End point title	Phase A: Number of subjects with suspected sign of meningism including febrile convulsions
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End point description:

Any = Occurrence of meningism including febrile convulsions regardless of intensity grade.

End point type	Secondary
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End point timeframe:

Within 43 days (Day 0-42) post-vaccination period following each dose

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	784	795	256	
Units: Participants				
Meningism, Dose 1	1	0	0	
Meningism, Dose 2 (N=758;773;247)	0	1	0	

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Phase A: Number of subjects reporting unsolicited Adverse Events (AEs)**

End point title	Phase A: Number of subjects reporting unsolicited Adverse Events (AEs)
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End point description:

Unsolicited AE assessed included any AE 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 = Occurrence of any unsolicited symptom regardless of intensity grade or relation to vaccination.

End point type	Secondary
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End point timeframe:

Within 43 days (Day 0-42) post-vaccination period following each dose

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	807	812	268	
Units: Participants				
Any AE(s), Dose 1	301	303	82	
Any AE(s), Dose 2 (N=777;788;253)	239	258	90	

**Statistical analyses**

No statistical analyses for this end point

### Secondary: Phase A: Number of subjects reporting Serious Adverse Events (SAEs)

End point title	Phase A: Number of subjects reporting Serious Adverse Events (SAEs)
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End point description:

SAEs assessed included medical occurrences that resulted in death, were life-threatening, required hospitalisation or prolongation of hospitalisation or resulted in disability/incapacity. Any SAE = occurrence of SAE regardless of intensity grade or relation to vaccination.

End point type	Secondary
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End point timeframe:

From Day 0 until the end of Phase A (Year 2)

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2489	2487	827	
Units: Participants				
Participants	473	480	148	

### Statistical analyses

No statistical analyses for this end point

### Secondary: Phase A: Health Economics analysis of factors leading to indirect costs due to varicella illness

End point title	Phase A: Health Economics analysis of factors leading to indirect costs due to varicella illness
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End point description:

Parameters assessed: 1. Number of hours/days lost from work by parents/guardians as a result of taking care of their child due to varicella. 2. Number of hours/days the child lost attendance in: day care/childminder, school, or in any extra-curricular activities (e.g. sports or recreation or any type of organised leisure activities) due to varicella. 3. Number of hours/days spent by a nurse, a babysitter or any type of existing paid caregiver to look after the child (if applicable).

End point type	Secondary
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End point timeframe:

During Phase A (from Day 0 up to Year 2)

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	37	246	201	
Units: Hours				
arithmetic mean (standard deviation)				
Time lost from work [hours]	31.5 (± 22.9)	40.5 (± 31.4)	48.1 (± 35.3)	
Time lost for subjects [hours]	66.4 (± 86)	49.5 (± 31.9)	54.5 (± 36.4)	
Time of requested assistance [hours]	34 (± 31.1)	35.2 (± 51.6)	35.4 (± 31.3)	



## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase B: Number of subjects with confirmed varicella case

End point title	Phase B: Number of subjects with confirmed varicella case
-----------------	---

End point description:

Confirmed varicella case = A case that met the clinical case definition at least in the opinion of the investigator and was confirmed by laboratory test [PCR (+)] OR a case that met the clinical definition confirmed by the IDMC and was epidemiologically linked [Epi (+)] to a valid index case.

End point type	Secondary
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End point timeframe:

From beginning of Phase B (Year 2) up to study end (Year 10)

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1800	1591	396	
Units: Participants				
Participants	38	225	149	

## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase B: Vaccine efficacy in subjects with confirmed varicella case

End point title	Phase B: Vaccine efficacy in subjects with confirmed varicella case <sup>[6]</sup>
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End point description:

VE was defined as efficacy of one dose of Varilrix or two doses of Priorix-Tetra in preventing confirmed varicella cases. Confirmed varicella case = A case that met the clinical case definition at least in the opinion of the investigator and was confirmed by laboratory test [PCR (+)] OR a case that met the clinical definition confirmed by the IDMC and was epidemiologically linked [Epi (+)] to a valid index case.

End point type	Secondary
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End point timeframe:

From the beginning of Phase B (Year 2) up to study end (Year 10)

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The results in this end point were tabulated as vaccine efficacy of Varilrix when compared to Priorix and vaccine efficacy of Priorix-Tetra when compared to Priorix. This endpoint therefore presents the results for groups applicable for this analysis (i.e., MMRV & OKAH Groups).

End point values	MMRV Group	OKAH Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1800	1591		
Units: Percentage				
number (confidence interval 95%)	95.855 (94.075 to 97.101)	69.812 (62.848 to 75.47)		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase B: Number of subjects with moderate or severe confirmed varicella case

End point title	Phase B: Number of subjects with moderate or severe confirmed varicella case
-----------------	--

End point description:

Confirmed varicella case = A case that met the clinical case definition at least in the opinion of the investigator and was confirmed by laboratory test [PCR (+)] OR a case that met the clinical definition confirmed by the IDMC and was epidemiologically linked [Epi (+)] to a valid index case. Moderately severe disease = 8-15 points; severe disease:  $\geq 16$  points (scored by IDMC using the modified Vázquez scale).

End point type	Secondary
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End point timeframe:

From the beginning of Phase B (Year 2) up to study end (Year 10)

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2279	2266	744	
Units: Participants				
Participants	6	67	176	

## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase B: Vaccine efficacy in subjects with moderate or severe confirmed varicella case

End point title	Phase B: Vaccine efficacy in subjects with moderate or severe confirmed varicella case <sup>[7]</sup>
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End point description:

VE was defined as efficacy of one dose of Varilrix or two doses of Priorix-Tetra in preventing moderate or severe confirmed varicella cases. Confirmed varicella case = A case that met the clinical case definition at least in the opinion of the investigator and was confirmed by laboratory test [PCR (+)] OR a case that met the clinical definition confirmed by the IDMC and was epidemiologically linked [Epi (+)] to a valid index case.

Moderately severe disease = 8-15 points; severe disease:  $\geq 16$  points (scored by IDMC using the

modified Vázquez scale).

End point type	Secondary
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End point timeframe:

From the beginning of Phase B (Year 2) up to study end (Year 10)

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The results in this end point were tabulated as vaccine efficacy of Varilrix when compared to Priorix and vaccine efficacy of Priorix-Tetra when compared to Priorix. This endpoint therefore presents the results for groups applicable for this analysis (i.e., MMRV & OKAH Groups).

End point values	MMRV Group	OKAH Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2279	2266		
Units: Percentage				
number (confidence interval 95%)	99.072 (97.907 to 99.589)	89.532 (86.126 to 92.102)		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase B: Number of subjects with probable or confirmed varicella case

End point title	Phase B: Number of subjects with probable or confirmed varicella case
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End point description:

Probable or confirmed varicella = An illness with acute onset of diffuse, generalized maculopapulovesicular rash (i.e. spots, papules and/or vesicles) without other apparent cause.

End point type	Secondary
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End point timeframe:

From the beginning of Phase B (Year 2) up to study end (Year 10)

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1800	1591	396	
Units: Participants				
Participants	49	237	152	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase B: Vaccine efficacy in subjects with probable or confirmed varicella case

End point title	Phase B: Vaccine efficacy in subjects with probable or
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## End point description:

VE was defined as efficacy of one dose of Varilrix or two doses of Priorix-Tetra in preventing probable or confirmed varicella cases. Probable or confirmed varicella = An illness with acute onset of diffuse, generalized maculopapulovesicular rash (i.e. spots, papules and/or vesicles) without other apparent cause.

End point type	Secondary
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## End point timeframe:

From the beginning of Phase B (Year 2) up to study end (Year 10)

## Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The results in this end point were tabulated as vaccine efficacy of Varilrix when compared to Priorix and vaccine efficacy of Priorix-Tetra when compared to Priorix. This endpoint therefore presents the results for groups applicable for this analysis (i.e., MMRV & OKAH Groups).

End point values	MMRV Group	OKAH Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1800	1591		
Units: Percentage				
number (confidence interval 95%)	94.816 (92.838 to 96.248)	68.932 (61.893 to 74.671)		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase B: Characteristics of varicella cases

End point title	Phase B: Characteristics of varicella cases
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## End point description:

Varicella cases were characterized by type, number and character of lesions, duration of rash, incidence of fever, systemic signs, the assessment by investigator, complications, treatment, outcome and intensity of severity.

End point type	Secondary
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## End point timeframe:

From the beginning of Phase B (Year 2) up to study end (Year 10)

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	38	225	149	
Units: Participants				
Number of varicella cases by subject, 1	38	223	148	
Number of varicella cases by subject, 2	0	2	1	
Varicella type, Any	38	225	149	
Varicella type, Confirmed	38	225	149	
Varicella type, Confirmed PCR	31	207	140	
Varicella type, Confirmed EPI	7	18	9	
Varicella type, Confirmed or Probable	38	225	149	

Varicella type, No case	0	0	0	
Rash: number of lesions, 1-50	32	173	76	
Rash: number of lesions, 51-100	5	35	39	
Rash: number of lesions, 101-500	1	15	27	
Rash: number of lesions, 501+	0	0	7	
Rash: number of lesions, Missing	0	2	0	
Character of most lesions, Macular	4	6	1	
Character of most lesions, Papular	16	108	63	
Character of most lesions, Vesicular	16	100	81	
Character of most lesions, Haemorrhagic	2	6	4	
Character of most lesions, Missing	0	5	0	
Duration of rash, 0 days	0	0	0	
Duration of rash, 1-5 days	23	140	68	
Duration of rash, 6-10 days	10	67	61	
Duration of rash, 11-15 days	5	13	19	
Duration of rash, 16+ days	0	0	0	
Duration of rash, Missing	0	5	1	
Max. number of lesions [investigator], 1-50	32	173	76	
Max. number of lesions [investigator], 51-100	5	35	39	
Max. number of lesions [investigator], 101-500	1	15	27	
Max. number of lesions [investigator], 501+	0	0	7	
Max. number of lesions [investigator], Missing	0	2	0	
Fever, No fever	37	212	100	
Fever, 38.8°C to 39.9°C	1	13	43	
Fever, 40+ °C	0	0	6	
Systemic sign, Pain in back or abdomen	6	27	27	
Systemic sign, Interstitial pneumonia	0	0	0	
Systemic sign, Encephalitis	0	0	0	
Assessment by investigator, Does not appear ill	28	159	62	
Assessment by investigator, Moderately ill	10	64	80	
Assessment by investigator, Severely ill	0	1	6	
Assessment by investigator, Missing	0	1	1	
Complications, Yes	0	0	0	
Complications, No	38	222	147	
Complications, Missing	0	3	2	
Treatment, Yes	15	115	91	
Treatment, No	23	106	56	
Treatment, Missing	0	4	2	
Outcome, Recovered/resolved	38	224	148	
Outcome, Recovered/resolved with sequelae	0	0	0	
Outcome, Missing	0	1	1	
Intensity of severity, Mild	34	198	91	
Intensity of severity, Moderately severe	4	27	54	
Intensity of severity, Severe	0	0	4	

## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase B: Immune response to varicella vaccine with respect to anti-Varicella Zoster Virus (anti-VZV) antibody concentrations

End point title	Phase B: Immune response to varicella vaccine with respect to anti-Varicella Zoster Virus (anti-VZV) antibody concentrations
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End point description:

Anti-VZV antibody concentrations are presented as Geometric Mean Concentrations (GMCs), expressed in milliinternational units per milliliter (mIU/mL).

End point type	Secondary
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End point timeframe:

At Year 4, Year 6, Year 8 and Year 10 time points

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1342	1142	242	
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-VZV, Year 4 (N=1342;1142;242)	501.3 (467.8 to 537.1)	272.7 (246.2 to 302.1)	32.4 (26.1 to 40.4)	
Anti-VZV, Year 6 (N=1292;1021;176)	680.6 (635.7 to 728.8)	417.6 (379.9 to 459)	91.8 (66.3 to 126.9)	
Anti-VZV, Year 8 (N=1146;828;117)	512.5 (480.3 to 546.8)	418.5 (383.2 to 457.1)	146.9 (99.6 to 216.6)	
Anti-VZV, Year 10 (N=1169;831;111)	471.3 (443.2 to 501.2)	404.6 (373 to 438.8)	219.6 (149.2 to 323.3)	

## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase B: Number of subjects with anti-VZV antibody concentrations above the cut-off value

End point title	Phase B: Number of subjects with anti-VZV antibody concentrations above the cut-off value
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End point description:

The anti-VZV antibody concentration cut-off value assessed was greater than or equal to ( $\geq$ ) 25 mIU/mL, in the sera of subjects seronegative before vaccination.

End point type	Secondary
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End point timeframe:

At Year 4, Year 6, Year 8 and Year 10 time points

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1342	1142	242	
Units: Participants				
Anti-VZV, Year 4 (N=1342;1142;242)	1330	1061	73	
Anti-VZV, Year 6 (N=1292;1021;176)	1289	986	97	
Anti-VZV, Year 8 (N=1146;828;117)	1142	806	78	
Anti-VZV, Year 10 (N=1169;831;111)	1164	818	81	

### Statistical analyses

No statistical analyses for this end point

### Secondary: Phase B: Immune response to measles with respect to anti-measles antibody concentrations

End point title	Phase B: Immune response to measles with respect to anti-measles antibody concentrations
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End point description:

Anti-measles antibody concentrations are presented as Geometric Mean Concentrations (GMCs), expressed in milliinternational units per milliliter (mIU/mL).

End point type	Secondary
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End point timeframe:

At Year 4, Year 6, Year 8 and Year 10 time points

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	410	409	137	
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-measles, Year 4 (N=410;409;137)	3290.9 (3025.8 to 3579.2)	1803.5 (1635.8 to 1988.5)	1724.4 (1431.7 to 2077)	
Anti-measles, Year 6 (N=406;221;137)	2795.9 (2544.7 to 3072)	1727.7 (1514.3 to 1971.1)	1369 (1125.7 to 1665)	
Anti-measles, Year 8 (N=357;125;119)	2342 (2115.3 to 2593)	1575.1 (1296.9 to 1913.1)	1175.5 (963.6 to 1434)	
Anti-measles, Year 10 (N=344;39;116)	1857.2 (1664 to 2072.8)	997.5 (726.7 to 1369.1)	913.6 (747 to 1117.4)	

## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase B: Number of subjects with anti-measles antibody concentrations above the cut-off value

End point title	Phase B: Number of subjects with anti-measles antibody concentrations above the cut-off value
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End point description:

The anti-measles antibody concentration cut-off value assessed was  $\geq 150$  mIU/mL, in the sera of subjects seronegative before vaccination.

End point type	Secondary
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End point timeframe:

At Year 4, Year 6, Year 8 and Year 10 time points

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	410	409	137	
Units: Participants				
Anti-measles, Year 4 (N=410;409;137)	407	402	131	
Anti-measles, Year 6 (N=406;221;137)	402	218	128	
Anti-measles, Year 8 (N=357;125;119)	353	121	113	
Anti-measles, Year 10 (N=344;39;116)	339	39	109	

## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase B: Immune response to mumps with respect to anti-mumps antibody concentrations

End point title	Phase B: Immune response to mumps with respect to anti-mumps antibody concentrations
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End point description:

Anti-mumps antibody concentrations are presented as Geometric Mean Concentrations (GMCs), expressed in units per milliliter (U/mL).

End point type	Secondary
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End point timeframe:

At Year 4, Year 6, Year 8 and Year 10 time points



End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	407	407	136	
Units: U/mL				
geometric mean (confidence interval 95%)				
Anti-mumps, Year 4 (N=407;407;136)	1088.9 (974.9 to 1216.3)	905.3 (810 to 1011.9)	1059.1 (878.9 to 1276.3)	
Anti-mumps, Year 6 (N=398;217;132)	999.7 (897.4 to 1113.7)	920.5 (800.3 to 1058.8)	1030.3 (879.1 to 1207.6)	
Anti-mumps, Year 8 (N=348;120;117)	875.7 (781.9 to 980.9)	865.7 (718.3 to 1043.3)	869.1 (723.3 to 1044.2)	
Anti-mumps, Year 10 (N=339;37;115)	889.3 (794.4 to 995.6)	1054 (797.2 to 1393.6)	912.7 (759.5 to 1096.8)	

### Statistical analyses

No statistical analyses for this end point

### Secondary: Phase B: Number of subjects with anti-mumps antibody concentrations above the cut-off value

End point title	Phase B: Number of subjects with anti-mumps antibody concentrations above the cut-off value
End point description:	The anti-mumps antibody concentration cut-off value assessed was $\geq 231$ U/mL, in the sera of subjects seronegative before vaccination.
End point type	Secondary
End point timeframe:	At Year 4, Year 6, Year 8 and Year 10 time points

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	407	407	136	
Units: Participants				
Anti-mumps, Year 4 (N=407;407;136)	368	357	123	
Anti-mumps, Year 6 (N=398;217;132)	360	196	127	
Anti-mumps, Year 8 (N=348;120;117)	305	107	108	
Anti-mumps, Year 10 (N=339;37;115)	305	36	108	

### Statistical analyses

No statistical analyses for this end point

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**Secondary: Phase B: Immune response to rubella with respect to anti-rubella antibody concentrations**

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End point title	Phase B: Immune response to rubella with respect to anti-rubella antibody concentrations
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End point description:

Anti-rubella antibody concentrations are presented as Geometric Mean Concentrations (GMCs), expressed in international units per milliliter (IU/mL).

End point type	Secondary
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End point timeframe:

At Year 4, Year 6, Year 8 and Year 10 time points

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End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	407	410	137	
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-rubella, Year 4 (N=407;410;137)	44.4 (40.9 to 48.3)	50.8 (46.8 to 55.2)	49 (42.9 to 55.9)	
Anti-rubella, Year 6 (N=403;224;137)	30.1 (27.9 to 32.4)	34 (30.6 to 37.7)	33.3 (29.2 to 37.9)	
Anti-rubella, Year 8 (N=354;124;119)	20.8 (19 to 22.9)	26.7 (22.7 to 31.5)	23.3 (19.8 to 27.3)	
Anti-rubella, Year 10 (N=342;39;116)	18.8 (17 to 20.7)	29.2 (22.7 to 37.7)	20.8 (17.6 to 24.6)	

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**Statistical analyses**

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No statistical analyses for this end point

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**Secondary: Phase B: Number of subjects with anti-rubella antibody concentrations above the cut-off value**

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End point title	Phase B: Number of subjects with anti-rubella antibody concentrations above the cut-off value
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End point description:

The anti-rubella antibody concentration cut-off value assessed was  $\geq 4$  IU/mL, in the sera of subjects seronegative before vaccination.

End point type	Secondary
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End point timeframe:

At Year 4, Year 6, Year 8 and Year 10 time points

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End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	407	410	137	
Units: Participants				
Anti-rubella, Year 4 (N=407;410;137)	407	408	137	
Anti-rubella, Year 6 (N=403;224;137)	402	222	136	
Anti-rubella, Year 8 (N=354;124;119)	347	120	116	
Anti-rubella, Year 10 (N=342;39;116)	334	39	112	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase B: Characteristics of zoster cases

End point title	Phase B: Characteristics of zoster cases <sup>[9]</sup>
End point description:	
Zoster cases were characterized by number and character of lesions, duration of rash, incidence of fever, systemic signs, the assessment by investigator, complications, treatment, outcome and intensity of severity.	
End point type	Secondary
End point timeframe:	
From 6 weeks after Dose 2 until study end (Year 10)	

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.  
Justification: No subjects in the MMRV group reported zoster cases. This endpoint therefore presents the results for OKAH & MMR Groups only.

End point values	OKAH Group	MMR Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	2		
Units: Participants				
Rash: number of lesions, 1-50	4	2		
Rash: number of lesions, 51-100	0	0		
Rash: number of lesions, 101-500	0	0		
Rash: number of lesions, 501+	0	0		
Character of most lesions, Macular	0	0		
Character of most lesions, Papular	2	1		
Character of most lesions, Vesicular	2	1		
Character of most lesions, Haemorrhagic	0	0		
Duration of rash, 0 days	0	0		
Duration of rash, 1-5 days	0	1		
Duration of rash, 6-10 days	1	0		
Duration of rash, 11-15 days	3	1		
Duration of rash, 16+ days	0	0		
Max. number of lesions [investigator], 1-50	4	2		
Max. number of lesions [investigator], 51-100	0	0		

Max. number of lesions [investigator], 101-500	0	0		
Max. number of lesions [investigator], 501+	0	0		
Fever, No fever	4	2		
Fever, 38.8°C to 39.9°C	0	0		
Fever, 40+ °C	0	0		
Systemic signs, Pain in back or abdomen	2	1		
Systemic signs, Interstitial pneumonia	0	0		
Systemic signs, Encephalitis	0	0		
Assessment by investigator, Does not appear ill	3	2		
Assessment by investigator, Moderately ill	1	0		
Assessment by investigator, Severely ill	0	0		
Complications, Yes	0	0		
Complications, No	4	2		
Treatment, Yes	2	1		
Treatment, No	2	1		
Outcome, Recovered/resolved	4	2		
Outcome, Recovered/resolved with sequelae	0	0		
Intensity of severity, Mild	4	2		
Intensity of severity, Moderately severe	0	0		
Intensity of severity, Severe	0	0		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase B: Number of subjects reporting Serious Adverse Events (SAEs)

End point title	Phase B: Number of subjects reporting Serious Adverse Events (SAEs)
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End point description:

SAEs assessed included medical occurrences that resulted in death, were life-threatening, required hospitalisation or prolongation of hospitalisation or resulted in disability/incapacity. Any SAE = occurrence of SAE regardless of intensity grade or relation to vaccination.

End point type	Secondary
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End point timeframe:

From the beginning of Phase B (Year 2) up to study end (Year 10)

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1961	1978	641	
Units: Participants				
Participants	290	317	93	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase B: Health Economics analysis of factors leading to indirect costs due to varicella illness

End point title	Phase B: Health Economics analysis of factors leading to indirect costs due to varicella illness
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End point description:

Parameters assessed: 1. Number of hours/days lost from work by parents/guardians as a result of taking care of their child due to varicella. 2. Number of hours/days the child lost attendance in: day care/childminder, school, or in any extra-curricular activities (e.g. sports or recreation or any type of organised leisure activities) due to varicella. 3. Number of hours/days spent by a nurse, a babysitter or any type of existing paid caregiver to look after the child (if applicable).

End point type	Secondary
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End point timeframe:

During Phase B

End point values	MMRV Group	OKAH Group	MMR Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	38	227	150	
Units: Hours				
arithmetic mean (standard deviation)				
Time lost from work [hours]	42.8 (± 44.1)	44.6 (± 31.1)	57.8 (± 36.8)	
Time lost for subjects [hours]	40.7 (± 35.6)	48 (± 34.1)	57.2 (± 36.1)	
Time of requested assistance [hours]	0 (± 0)	45.7 (± 21.5)	49.4 (± 50)	

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Solicited local AEs: 4-days (Days 0-3) post dose 1 (Day 0) and dose 2 (Day 42). Solicited general and unsolicited AEs: 43-days (Days 0-42) post dose 1 (Day 0) and dose 2 (Day 42). Serious adverse events: From Day 0 up to the end of study (Year 10).

Adverse event reporting additional description:

For the systematically assessed other (non-serious) adverse events, the number of participants at risk included those from Total Vaccinated Cohort who had the symptom sheet completed.

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	12.1
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### Reporting groups

Reporting group title	MMRV Group
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Reporting group description:

Subjects in this group received 2 doses of Priorix-Tetra vaccine, administered subcutaneously in the deltoid region of the left arm, one at Day 0 (Visit 1) and the other at Day 42 (Visit 2).

Reporting group title	MMR Group
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Reporting group description:

Subjects in this group received 2 doses of Priorix, administered subcutaneously in the deltoid region of the left arm, one at Day 0 (Visit 1) and the other at Day 42 (Visit 2).

Reporting group title	OKAH Group
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Reporting group description:

Subjects in this group received 1 dose of Priorix at Day 0 (Visit 1) and 1 dose of Varilrix at Day 42 (Visit 2). Both vaccines were administered subcutaneously in the deltoid region of the left arm.

Serious adverse events	MMRV Group	MMR Group	OKAH Group
Total subjects affected by serious adverse events			
subjects affected / exposed	649 / 2489 (26.07%)	208 / 827 (25.15%)	681 / 2487 (27.38%)
number of deaths (all causes)	1	0	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute leukaemia			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Acute lymphocytic leukaemia			
subjects affected / exposed	2 / 2489 (0.08%)	1 / 827 (0.12%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Acute lymphocytic leukaemia recurrent			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Astrocytoma, low grade			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign bone neoplasm			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Laryngeal papilloma			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipoma			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medulloblastoma			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melanocytic naevus			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm			

subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephroblastoma			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Neuroblastoma			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Osteochondroma			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian germ cell teratoma benign			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papilloma			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyosarcoma			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin papilloma			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Teratoma			



subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Circulatory collapse			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kawasaki's disease			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitis			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Circumcision			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Accidental death			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Chest pain			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Crying			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cyst			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Granuloma			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperpyrexia			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthermia malignant			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ill-defined disorder			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyp			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			

subjects affected / exposed	2 / 2489 (0.08%)	1 / 827 (0.12%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue inflammation			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Allergic oedema			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Allergy to arthropod sting			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic reaction			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactoid reaction			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atopy			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug hypersensitivity			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			

subjects affected / exposed	2 / 2489 (0.08%)	1 / 827 (0.12%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immunodeficiency			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Acquired phimosis			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Balanoposthitis			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Penile adhesion			
subjects affected / exposed	3 / 2489 (0.12%)	1 / 827 (0.12%)	4 / 2487 (0.16%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Penis disorder			
subjects affected / exposed	3 / 2489 (0.12%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular appendage torsion			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular atrophy			

subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular disorder			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular retraction			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Adenoidal hypertrophy			
subjects affected / exposed	111 / 2489 (4.46%)	39 / 827 (4.72%)	123 / 2487 (4.95%)
occurrences causally related to treatment / all	0 / 116	0 / 39	0 / 129
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asphyxia			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Asthma			
subjects affected / exposed	11 / 2489 (0.44%)	5 / 827 (0.60%)	8 / 2487 (0.32%)
occurrences causally related to treatment / all	0 / 13	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthmatic crisis			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	1 / 2489 (0.04%)	1 / 827 (0.12%)	0 / 2487 (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
Epistaxis			

subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperventilation			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal obstruction			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal oedema			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngospasm			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngeal pain			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			

subjects affected / exposed	1 / 2489 (0.04%)	1 / 827 (0.12%)	0 / 2487 (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
Pneumonia aspiration			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Rhinitis allergic			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status asthmaticus			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillar hypertrophy			
subjects affected / exposed	7 / 2489 (0.28%)	3 / 827 (0.36%)	6 / 2487 (0.24%)
occurrences causally related to treatment / all	0 / 7	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord thickening			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Abnormal behaviour			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adjustment disorder			

subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adjustment disorder with mixed anxiety and depressed mood			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Affective disorder			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Agitation			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Attention deficit/hyperactivity disorder			
subjects affected / exposed	3 / 2489 (0.12%)	0 / 827 (0.00%)	3 / 2487 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breath holding			
subjects affected / exposed	3 / 2489 (0.12%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enuresis			
subjects affected / exposed	1 / 2489 (0.04%)	1 / 827 (0.12%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Learning disorder			



subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental disorder			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurosis			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Nightmare			
subjects affected / exposed	1 / 2489 (0.04%)	1 / 827 (0.12%)	0 / 2487 (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
Psychomotor retardation			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Reading disorder			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tic			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Medical observation			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

Abdominal injury			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accident			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental exposure to product			
subjects affected / exposed	4 / 2489 (0.16%)	1 / 827 (0.12%)	10 / 2487 (0.40%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental overdose			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Animal bite			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropod sting			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bite			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain contusion			

subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burn oral cavity			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns second degree			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carbon monoxide poisoning			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chemical injury			
subjects affected / exposed	3 / 2489 (0.12%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chemical poisoning			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Child maltreatment syndrome			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	1 / 2489 (0.04%)	1 / 827 (0.12%)	0 / 2487 (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
Concussion			

subjects affected / exposed	23 / 2489 (0.92%)	7 / 827 (0.85%)	26 / 2487 (1.05%)
occurrences causally related to treatment / all	0 / 24	0 / 8	0 / 26
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	15 / 2489 (0.60%)	2 / 827 (0.24%)	13 / 2487 (0.52%)
occurrences causally related to treatment / all	0 / 15	0 / 2	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dislocation of vertebra			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exposure to toxic agent			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye contusion			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye injury			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	2 / 2489 (0.08%)	1 / 827 (0.12%)	3 / 2487 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			

subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm fracture			
subjects affected / exposed	6 / 2489 (0.24%)	0 / 827 (0.00%)	9 / 2487 (0.36%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed	3 / 2489 (0.12%)	2 / 827 (0.24%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body aspiration			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture			
subjects affected / exposed	1 / 2489 (0.04%)	1 / 827 (0.12%)	0 / 2487 (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
Fracture displacement			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	3 / 2487 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	8 / 2489 (0.32%)	0 / 827 (0.00%)	9 / 2487 (0.36%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heat stroke			

subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	5 / 2489 (0.20%)	0 / 827 (0.00%)	9 / 2487 (0.36%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaw fracture			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney contusion			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laceration			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Ligament sprain			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			

subjects affected / exposed	4 / 2489 (0.16%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver contusion			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal injury			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Near drowning			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck injury			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Open fracture			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			

subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic injury			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patella fracture			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Penile contusion			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Poisoning			
subjects affected / exposed	2 / 2489 (0.08%)	1 / 827 (0.12%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Poisoning deliberate			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	4 / 2489 (0.16%)	1 / 827 (0.12%)	6 / 2487 (0.24%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			



subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin wound			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fracture			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Struck by lightning			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	6 / 2489 (0.24%)	1 / 827 (0.12%)	9 / 2487 (0.36%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			

subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tongue injury			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth injury			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	2 / 2489 (0.08%)	2 / 827 (0.24%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulna fracture			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	3 / 2487 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venomous sting			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	4 / 2489 (0.16%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist fracture			

subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Anomaly of external ear congenital			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial septal defect			
subjects affected / exposed	1 / 2489 (0.04%)	1 / 827 (0.12%)	0 / 2487 (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
Choledochal cyst			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital cystic kidney disease			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital inguinal hernia			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital oral malformation			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cryptorchism			
subjects affected / exposed	3 / 2489 (0.12%)	0 / 827 (0.00%)	3 / 2487 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystic fibrosis			

subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Double ureter			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duane's syndrome			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hereditary pancreatitis			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernia congenital			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocele			
subjects affected / exposed	8 / 2489 (0.32%)	0 / 827 (0.00%)	5 / 2487 (0.20%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurofibromatosis			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Phimosis			
subjects affected / exposed	12 / 2489 (0.48%)	2 / 827 (0.24%)	5 / 2487 (0.20%)
occurrences causally related to treatment / all	0 / 12	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Primary ciliary dyskinesia			

subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thalassaemia beta			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia supraventricular			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cyanosis			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Long qt syndrome			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Palpitations			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			

subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Autism			
subjects affected / exposed	2 / 2489 (0.08%)	1 / 827 (0.12%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign rolandic epilepsy			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain injury			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cluster headache			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coordination abnormal			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysgraphia			

subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyslexia			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	4 / 2489 (0.16%)	1 / 827 (0.12%)	5 / 2487 (0.20%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paresis			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	21 / 2489 (0.84%)	4 / 827 (0.48%)	20 / 2487 (0.80%)
occurrences causally related to treatment / all	3 / 23	1 / 4	0 / 23
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	2 / 2489 (0.08%)	1 / 827 (0.12%)	4 / 2487 (0.16%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intellectual disability			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Language disorder			

subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorder			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral nerve palsy			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyneuropathy			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Postictal state			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			



subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	5 / 2487 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Speech disorder			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Speech disorder developmental			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	2 / 2489 (0.08%)	1 / 827 (0.12%)	4 / 2487 (0.16%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Abdominal lymphadenopathy			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Anaemia			
subjects affected / exposed	6 / 2489 (0.24%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic diathesis			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenic purpura			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			

subjects affected / exposed	1 / 2489 (0.04%)	1 / 827 (0.12%)	0 / 2487 (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
Leukopenia			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis			
subjects affected / exposed	7 / 2489 (0.28%)	1 / 827 (0.12%)	9 / 2487 (0.36%)
occurrences causally related to treatment / all	0 / 8	0 / 1	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Ear deformity acquired			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
External ear disorder			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoacusis			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inner ear disorder			

subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otorrhoea			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Astigmatism			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chalazion			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye haemorrhage			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid oedema			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammation of lacrimal passage			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papilloedema			

subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strabismus			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Visual impairment			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
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			
Abdominal discomfort			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	7 / 2489 (0.28%)	5 / 827 (0.60%)	14 / 2487 (0.56%)
occurrences causally related to treatment / all	0 / 7	0 / 5	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fissure			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal stenosis			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphthous ulcer			

subjects affected / exposed	3 / 2489 (0.12%)	0 / 827 (0.00%)	3 / 2487 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coeliac disease			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	3 / 2487 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dental caries			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	2 / 2489 (0.08%)	1 / 827 (0.12%)	4 / 2487 (0.16%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	4 / 2489 (0.16%)	0 / 827 (0.00%)	6 / 2487 (0.24%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			

subjects affected / exposed	6 / 2489 (0.24%)	2 / 827 (0.24%)	7 / 2487 (0.28%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	4 / 2489 (0.16%)	0 / 827 (0.00%)	4 / 2487 (0.16%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Functional gastrointestinal disorder			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	31 / 2489 (1.25%)	9 / 827 (1.09%)	22 / 2487 (0.88%)
occurrences causally related to treatment / all	0 / 34	0 / 9	0 / 25
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis erosive			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroduodenitis			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
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 disorder			
subjects affected / exposed	3 / 2489 (0.12%)	1 / 827 (0.12%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal inflammation			

subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroesophageal reflux disease			
subjects affected / exposed	1 / 2489 (0.04%)	1 / 827 (0.12%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	13 / 2489 (0.52%)	5 / 827 (0.60%)	16 / 2487 (0.64%)
occurrences causally related to treatment / all	0 / 13	0 / 6	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal haemorrhage			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine polyp			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip disorder			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Pancreatitis			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			

subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Teething			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth loss			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	6 / 2489 (0.24%)	1 / 827 (0.12%)	5 / 2487 (0.20%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	5 / 2489 (0.20%)	1 / 827 (0.12%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct obstruction			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder disorder			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			



subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis allergic			
subjects affected / exposed	6 / 2489 (0.24%)	3 / 827 (0.36%)	4 / 2487 (0.16%)
occurrences causally related to treatment / all	0 / 6	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis atopic			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug eruption			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Eczema			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema nodosum			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Henoch-schonlein purpura			

subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prurigo			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
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	1 / 2489 (0.04%)	1 / 827 (0.12%)	0 / 2487 (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
Rash papular			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash vesicular			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin burning sensation			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin hyperpigmentation			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic skin eruption			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			

subjects affected / exposed	4 / 2489 (0.16%)	1 / 827 (0.12%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Glomerulonephritis			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis acute			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis chronic			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Micturition disorder			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephritis			
subjects affected / exposed	2 / 2489 (0.08%)	1 / 827 (0.12%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			

subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pollakiuria			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proteinuria			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal haematoma			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	1 / 2489 (0.04%)	2 / 827 (0.24%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vesicoureteric reflux			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Endocrine disorder			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroiditis			

subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	3 / 2489 (0.12%)	2 / 827 (0.24%)	3 / 2487 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis reactive			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Arthropathy			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone disorder			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Exostosis			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fistula			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Growth retardation			

subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint effusion			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint swelling			
subjects affected / exposed	1 / 2489 (0.04%)	1 / 827 (0.12%)	0 / 2487 (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
Juvenile idiopathic arthritis			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Myopathy			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondrosis			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periostitis			

subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatoid arthritis			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rickets			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sacroiliitis			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scoliosis			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal pain			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovitis			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Torticollis			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trigger finger			

subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Infections and infestations</b>			
Abscess neck			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute sinusitis			
subjects affected / exposed	1 / 2489 (0.04%)	2 / 827 (0.24%)	4 / 2487 (0.16%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenoiditis			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenovirus infection			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Anal abscess			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	14 / 2489 (0.56%)	5 / 827 (0.60%)	12 / 2487 (0.48%)
occurrences causally related to treatment / all	0 / 14	0 / 5	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascariasis			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial diarrhoea			



subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	2 / 2489 (0.08%)	1 / 827 (0.12%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteriuria			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Body tinea			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Borrelia infection			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	1 / 2489 (0.04%)	2 / 827 (0.24%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	47 / 2489 (1.89%)	15 / 827 (1.81%)	51 / 2487 (2.05%)
occurrences causally related to treatment / all	0 / 55	0 / 15	0 / 65
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis haemophilus			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter gastroenteritis			

subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter infection			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis orbital			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic tonsillitis			
subjects affected / exposed	3 / 2489 (0.12%)	2 / 827 (0.24%)	9 / 2487 (0.36%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctivitis			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Croup infectious			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	3 / 2489 (0.12%)	1 / 827 (0.12%)	3 / 2487 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea infectious			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear infection			

subjects affected / exposed	4 / 2489 (0.16%)	0 / 827 (0.00%)	3 / 2487 (0.12%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eczema impetiginous			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis infectious			
subjects affected / exposed	5 / 2489 (0.20%)	6 / 827 (0.73%)	5 / 2487 (0.20%)
occurrences causally related to treatment / all	0 / 5	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterobiasis			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovirus infection			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epididymitis			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epstein-barr virus infection			

subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema infectiosum			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	1 / 2489 (0.04%)	1 / 827 (0.12%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye infection			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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 infection			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis viral			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	67 / 2489 (2.69%)	26 / 827 (3.14%)	71 / 2487 (2.85%)
occurrences causally related to treatment / all	0 / 74	0 / 28	0 / 79
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			

subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
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 bacterial			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
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 norovirus			
subjects affected / exposed	1 / 2489 (0.04%)	1 / 827 (0.12%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	27 / 2489 (1.08%)	13 / 827 (1.57%)	42 / 2487 (1.69%)
occurrences causally related to treatment / all	0 / 27	0 / 13	0 / 42
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	9 / 2487 (0.36%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	2 / 2489 (0.08%)	1 / 827 (0.12%)	4 / 2487 (0.16%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal bacterial overgrowth			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal viral infection			

subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
H1n1 influenza			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Helicobacter gastritis			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis a			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpangina			
subjects affected / exposed	3 / 2489 (0.12%)	2 / 827 (0.24%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious mononucleosis			
subjects affected / exposed	5 / 2489 (0.20%)	0 / 827 (0.00%)	7 / 2487 (0.28%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			

subjects affected / exposed	2 / 2489 (0.08%)	1 / 827 (0.12%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	39 / 2489 (1.57%)	8 / 827 (0.97%)	45 / 2487 (1.81%)
occurrences causally related to treatment / all	0 / 51	0 / 8	0 / 56
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	3 / 2487 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis aseptic			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis borrelia			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningococcal sepsis			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Molluscum contagiosum			

subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	3 / 2487 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal abscess			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	17 / 2489 (0.68%)	3 / 827 (0.36%)	6 / 2487 (0.24%)
occurrences causally related to treatment / all	0 / 17	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroborreliosis			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral herpes			
subjects affected / exposed	2 / 2489 (0.08%)	2 / 827 (0.24%)	3 / 2487 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchitis			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngitis fungal			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	17 / 2489 (0.68%)	3 / 827 (0.36%)	7 / 2487 (0.28%)
occurrences causally related to treatment / all	0 / 19	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			



subjects affected / exposed	5 / 2489 (0.20%)	0 / 827 (0.00%)	7 / 2487 (0.28%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media chronic			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overgrowth bacterial			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parotitis			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parvovirus b19 infection			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periodontitis			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	1 / 2489 (0.04%)	1 / 827 (0.12%)	0 / 2487 (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
Peritonsillar abscess			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	4 / 2487 (0.16%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			

subjects affected / exposed	20 / 2489 (0.80%)	2 / 827 (0.24%)	13 / 2487 (0.52%)
occurrences causally related to treatment / all	0 / 21	0 / 2	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Pharyngotonsillitis			
subjects affected / exposed	6 / 2489 (0.24%)	3 / 827 (0.36%)	10 / 2487 (0.40%)
occurrences causally related to treatment / all	0 / 6	0 / 3	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal cyst			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	70 / 2489 (2.81%)	30 / 827 (3.63%)	63 / 2487 (2.53%)
occurrences causally related to treatment / all	0 / 80	0 / 31	0 / 66
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pneumococcal			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudocroup			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			

subjects affected / exposed	3 / 2489 (0.12%)	3 / 827 (0.36%)	4 / 2487 (0.16%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	4 / 2489 (0.16%)	1 / 827 (0.12%)	7 / 2487 (0.28%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyoderma			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
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 tract infection			
subjects affected / exposed	4 / 2489 (0.16%)	2 / 827 (0.24%)	3 / 2487 (0.12%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			
subjects affected / exposed	1 / 2489 (0.04%)	1 / 827 (0.12%)	0 / 2487 (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
Rhinitis			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	3 / 2487 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotavirus infection			
subjects affected / exposed	1 / 2489 (0.04%)	1 / 827 (0.12%)	0 / 2487 (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
Salmonellosis			
subjects affected / exposed	6 / 2489 (0.24%)	1 / 827 (0.12%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scarlet fever			

subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	7 / 2489 (0.28%)	5 / 827 (0.60%)	4 / 2487 (0.16%)
occurrences causally related to treatment / all	0 / 7	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	23 / 2489 (0.92%)	7 / 827 (0.85%)	18 / 2487 (0.72%)
occurrences causally related to treatment / all	0 / 23	0 / 9	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis bacterial			
subjects affected / exposed	4 / 2489 (0.16%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis streptococcal			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxocariasis			

subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheitis			
subjects affected / exposed	9 / 2489 (0.36%)	3 / 827 (0.36%)	4 / 2487 (0.16%)
occurrences causally related to treatment / all	0 / 9	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	3 / 2487 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculosis of intrathoracic lymph nodes			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	8 / 2489 (0.32%)	3 / 827 (0.36%)	9 / 2487 (0.36%)
occurrences causally related to treatment / all	0 / 8	0 / 3	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	6 / 2489 (0.24%)	1 / 827 (0.12%)	3 / 2487 (0.12%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	3 / 2487 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral diarrhoea			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Viral infection			

subjects affected / exposed	4 / 2489 (0.16%)	4 / 827 (0.48%)	11 / 2487 (0.44%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral myositis			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral pharyngitis			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral tonsillitis			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	5 / 2489 (0.20%)	5 / 827 (0.60%)	9 / 2487 (0.36%)
occurrences causally related to treatment / all	0 / 6	0 / 5	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvitis			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	9 / 2489 (0.36%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 10	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	2 / 2489 (0.08%)	1 / 827 (0.12%)	3 / 2487 (0.12%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus inadequate control			

subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Hypoglycaemia			
subjects affected / exposed	2 / 2489 (0.08%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ketoacidosis			
subjects affected / exposed	0 / 2489 (0.00%)	1 / 827 (0.12%)	0 / 2487 (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
Lactose intolerance			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	2 / 2487 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			
subjects affected / exposed	0 / 2489 (0.00%)	0 / 827 (0.00%)	1 / 2487 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			
subjects affected / exposed	1 / 2489 (0.04%)	1 / 827 (0.12%)	3 / 2487 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight gain poor			

subjects affected / exposed	1 / 2489 (0.04%)	0 / 827 (0.00%)	0 / 2487 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 4.98 %

<b>Non-serious adverse events</b>	MMRV Group	MMR Group	OKAH Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	666 / 2489 (26.76%)	204 / 827 (24.67%)	641 / 2487 (25.77%)
General disorders and administration site conditions			
Injection site erythema			
subjects affected / exposed	244 / 2489 (9.80%)	43 / 827 (5.20%)	183 / 2487 (7.36%)
occurrences (all)	325	60	260
Injection site pain			
subjects affected / exposed	124 / 2489 (4.98%)	31 / 827 (3.75%)	111 / 2487 (4.46%)
occurrences (all)	165	37	146
Pyrexia			
subjects affected / exposed	604 / 2489 (24.27%)	188 / 827 (22.73%)	574 / 2487 (23.08%)
occurrences (all)	849	253	790



## **More information**

### **Substantial protocol amendments (globally)**

Were there any global substantial amendments to the protocol? No

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported