



Clinical trial results:

A Phase 2 Partially Observer-Blind Randomized Controlled Multicenter Dose- Ranging and Formulation-Finding Study of a new Novartis Meningococcal B Recombinant Vaccine evaluating the safety and immunogenicity when given concomitantly with routine vaccines in 2-month-old infants

Due to a system error, the data reported in v1 is not correct and has been removed from public view.

Summary

EudraCT number	2009-010106-11
Trial protocol	CZ IT HU
Global end of trial date	12 December 2011

Results information

Result version number	v2 (current)
This version publication date	01 June 2016
First version publication date	27 December 2014
Version creation reason	• Correction of full data set re-QC study because of EudraCT system glitch and updates to the results are required.

Trial information

Trial identification

Sponsor protocol code	V72P16
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00937521
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Vaccines and Diagnostics S.r.l.
Sponsor organisation address	Via Fiorentina, 1, Siena, Italy, 53100
Public contact	Posting Director, Novartis Vaccines and Diagnostics S.r.l., RegistryContactVaccinesUS@novartis.com
Scientific contact	Posting Director, Novartis Vaccines and Diagnostics S.r.l., RegistryContactVaccinesUS@novartis.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	06 November 2012
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	12 December 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Immunogenicity: To assess if any of seven different formulations of rMenB+OMV NZ or rMenB (no OMV) vaccine (Groups I-VI and VIII) induce sufficient immune response when given to healthy infants at 2, 3 and 4 months of age, as measured by percentage of subjects with serum bactericidal activity (SBA) titer $\geq 1:5$, at 1 month after the third vaccination. Safety: To assess if any of six different formulations of rMenB+OMV NZ or rMenB (no OMV) vaccine (Group II to VI; Group VIII) will reduce the incidence of fever ≥ 38.5 C (rectal) occurring within 3 days (day 1-3) following first vaccination as compared to rMenB+OMV NZ (Group I).

Protection of trial subjects:

This trial was conducted in accordance with the ethical principles that have their origin in the latest version of Declaration of Helsinki accepted by the local authorities, and that are consistent with Good Clinical Practices (GCPs) and the applicable regulatory requirement(s) for the country in which the trial is conducted, Good Clinical Practice (GCP) according to International Conference on Harmonisation (ICH) guidelines, and applicable Standard Operating Procedures (SOPs). Specifically, this trial was based on adequately performed laboratory and animal experimentation; the trial was conducted based on a protocol reviewed and approved by an EC; the trial was conducted by scientifically and medically qualified persons; the benefits of the study were in proportion to the risks; the rights and welfare of the subjects were respected; the physicians conducting the trial did not find the hazards to outweigh the potential benefits; each subject, or where applicable, each subject's legally acceptable representative(s) gave his or her written informed consent before any protocol-driven tests or evaluations were performed.

Background therapy:

Routine infant vaccines, InfanrixHexa® and Prevenar®.

Evidence for comparator:

N/A

Actual start date of recruitment	14 July 2009
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	6 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Hungary: 69
Country: Number of subjects enrolled	Italy: 448
Country: Number of subjects enrolled	Argentina: 5

Country: Number of subjects enrolled	Chile: 24
Country: Number of subjects enrolled	Czech Republic: 961
Worldwide total number of subjects	1507
EEA total number of subjects	1478

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	1
Infants and toddlers (28 days-23 months)	1506
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were enrolled from 79 sites in Czech Republic (subjects were enrolled from 71 of these sites and 8 sites had a coordinating role only); 8 sites in Hungary; 6 sites in Italy, 1 site each in Argentina and Chile.

Pre-assignment

Screening details:

24 enrolled subjects were not included in the study.

Period 1

Period 1 title	Overall Study - Prior to Booster Dose
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Blinding implementation details:

The trial was partially observer-blinded. The inclusion of the control group receiving Menjugate (MenC group) concomitantly with routine vaccination allowed blinding of the subject's parents/legal guardians, as well as blinding of the investigator and the study staff who evaluated the subjects (observers). However, blinding was not possible for subjects who received prophylactic administration of oral paracetamol (Par+B+OMV).

Arms

Are arms mutually exclusive?	Yes
Arm title	B+OMV (Group I)

Arm description:

Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation I) and routine vaccines at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.

Arm type	Experimental
Investigational medicinal product name	4CMenB
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

4 doses of 0.5 mL

Investigational medicinal product name	Prevenar
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

4 doses of 0.5 mL

Investigational medicinal product name	MenC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

one dose of 0.5 mL

Investigational medicinal product name	Infanrix Hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details: 4 doses of 0.5 mL	
Arm title	B+ ½ OMV (Group II)

Arm description:

Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation II) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.

Arm type	Experimental
Investigational medicinal product name	rMenB+1/2 OMV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

4 doses of 0.5 mL

Investigational medicinal product name	Prevenar
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

4 doses of 0.5 mL

Investigational medicinal product name	MenC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

one dose of of 0.5 mL

Investigational medicinal product name	Infanrix Hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

4 doses of 0.5 mL

Arm title	B+1/4 OMV (Group III)
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Arm description:

Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation III) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.

Arm type	Experimental
Investigational medicinal product name	rMenB+1/4 OMV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:	
4 doses of 0.5 mL	
Investigational medicinal product name	Prevenar
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
4 doses of 0.5 mL	
Investigational medicinal product name	MenC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
one dose of of 0.5 mL	
Investigational medicinal product name	Infanrix Hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
4 doses of 0.5 mL	
Arm title	B (Group IV)
Arm description:	
Subjects in this group received one dose of meningococcal B recombinant (rMenB) adsorbed vaccine (formulation IV) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.	
Arm type	Experimental
Investigational medicinal product name	rMenB
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
4 doses of 0.5 mL	
Investigational medicinal product name	Infanrix Hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
4 doses of 0.5 mL	
Investigational medicinal product name	Prevenar
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
4 doses of 0.5 mL	
Investigational medicinal product name	MenC
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: one dose of of 0.5 mL	

Arm title	½ (B+OMV) (Group V)
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Arm description:

Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation V) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.

Arm type	Experimental
Investigational medicinal product name	1/2 (rMenB+OMV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

4 doses of 0.5 mL

Investigational medicinal product name	Prevenar
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

4 doses of 0.5 mL

Investigational medicinal product name	MenC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

one dose of of 0.5 mL

Investigational medicinal product name	Infanrix Hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

4 doses of 0.5 mL

Arm title	PH2 B+OMV (Group VI)
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Arm description:

Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation VI) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.

Arm type	Experimental
Investigational medicinal product name	4CMenB
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

4 doses of 0.5 mL

Investigational medicinal product name	Infanrix Hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
4 doses of 0.5 mL	
Investigational medicinal product name	Prevenar
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
4 doses of 0.5 mL	
Investigational medicinal product name	MenC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
one dose of of 0.5 mL	
Arm title	MenC (Group VII)
Arm description:	
Subjects received one dose of meningococcal C conjugate vaccine (Menjugate®; Men C) and routine vaccine at 2,3,4 months of age, one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation VII) and routine vaccine at 12 months of age, one dose of rMenB+OMV NZ and one dose of MenC at 13 months of age.	
Arm type	Experimental
Investigational medicinal product name	4CMenB
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
two doses of 0.5 mL	
Investigational medicinal product name	Infanrix Hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
4 doses of 0.5 mL	
Investigational medicinal product name	Prevenar
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
4 doses of 0.5 mL	
Investigational medicinal product name	MenC
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: five doses of 0.5 mL each	
Arm title	Par+B+OMV (Group VIII)
Arm description: Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation I) with paracetamol and routine vaccines at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.	
Arm type	Experimental
Investigational medicinal product name	4CMenB
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: 4 doses of 0.5 mL	
Investigational medicinal product name	MenC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: one dose of of 0.5 mL	
Investigational medicinal product name	Prevenar
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details: 4 doses of 0.5 mL	
Investigational medicinal product name	Infanrix Hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details: 4 doses of 0.5 mL	
Investigational medicinal product name	Paracetamol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use
Dosage and administration details: 10-15 mg/Kg	

Number of subjects in period 1	B+OMV (Group I)	B+½ OMV (Group II)	B+1/4 OMV (Group III)
Started	188	190	192
Completed	185	185	186
Not completed	3	5	6
Adverse Event or Death	-	-	2
Consent withdrawn by subject	2	1	3
Lost to follow-up	-	-	1
Inappropriate Enrollment	-	4	-
Protocol deviation	1	-	-

Number of subjects in period 1	B (Group IV)	½ (B+OMV) (Group V)	PH2 B+OMV (Group VI)
Started	188	191	188
Completed	187	188	187
Not completed	1	3	1
Adverse Event or Death	-	-	-
Consent withdrawn by subject	-	1	-
Lost to follow-up	1	-	-
Inappropriate Enrollment	-	2	1
Protocol deviation	-	-	-

Number of subjects in period 1	MenC (Group VII)	Par+B+OMV (Group VIII)
Started	186	184
Completed	181	183
Not completed	5	1
Adverse Event or Death	1	-
Consent withdrawn by subject	2	1
Lost to follow-up	-	-
Inappropriate Enrollment	1	-
Protocol deviation	1	-

Period 2

Period 2 title	Booster Phase
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Blinding implementation details:

The trial was partially observer-blinded. The inclusion of the control group receiving Menjugate (MenC group) concomitantly with routine vaccination allowed blinding of the subject's parents/legal guardians, as well as blinding of the investigator and the study staff who evaluated the subjects (observers).

However, blinding was not possible for subjects who received prophylactic administration of oral paracetamol (Par+B+OMV).

Arms

Are arms mutually exclusive?	Yes
Arm title	B+OMV (Group I)

Arm description:

Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation I) and routine vaccines at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.

Arm type	Experimental
Investigational medicinal product name	4CMenB
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

4 doses of 0.5 mL

Investigational medicinal product name	Infanrix Hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

4 doses of 0.5 mL

Investigational medicinal product name	Prevenar
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

4 doses of 0.5 mL

Investigational medicinal product name	MenC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

one dose of 0.5 mL

Arm title	B+ ½ OMV (Group II)
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Arm description:

Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation II) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.

Arm type	Experimental
Investigational medicinal product name	rMenB+1/2 OMV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

4 doses of 0.5 mL

Investigational medicinal product name	Prevenar
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
4 doses of 0.5 mL	
Investigational medicinal product name	MenC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
one dose of of 0.5 mL	
Investigational medicinal product name	Infanrix Hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
4 doses of 0.5 mL	
Arm title	B+1/4 OMV (Group III)
Arm description:	
Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation III) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.	
Arm type	Experimental
Investigational medicinal product name	rMenB+1/4 OMV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
4 doses of 0.5 mL	
Investigational medicinal product name	Prevenar
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
4 doses of 0.5 mL	
Investigational medicinal product name	MenC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
one dose of of 0.5 mL	
Investigational medicinal product name	Infanrix Hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection

Routes of administration	Intramuscular use
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Dosage and administration details:

4 doses of 0.5 mL

Arm title	B (Group IV)
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Arm description:

Subjects in this group received one dose of meningococcal B recombinant (rMenB) adsorbed vaccine (formulation IV) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.

Arm type	Experimental
Investigational medicinal product name	rMenB
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

4 doses of 0.5 mL

Investigational medicinal product name	Infanrix Hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

4 doses of 0.5 mL

Investigational medicinal product name	Prevenar
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

4 doses of 0.5 mL

Investigational medicinal product name	MenC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

one dose of 0.5 mL

Arm title	½ (B+OMV) (Group V)
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Arm description:

Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation V) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.

Arm type	Experimental
Investigational medicinal product name	1/2 (rMenB+OMV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

4 doses of 0.5 mL

Investigational medicinal product name	Prevenar
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
4 doses of 0.5 mL	
Investigational medicinal product name	MenC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
one dose of of 0.5 mL	
Investigational medicinal product name	Infanrix Hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
4 doses of 0.5 mL	
Arm title	PH2 B+OMV (Group VI)
Arm description:	
Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation VI) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.	
Arm type	Experimental
Investigational medicinal product name	4CMenB
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
4 doses of 0.5 mL	
Investigational medicinal product name	MenC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
one dose of of 0.5 mL	
Investigational medicinal product name	Infanrix Hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
4 doses of 0.5 mL	
Investigational medicinal product name	Prevenar
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection

Routes of administration	Intramuscular use
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Dosage and administration details:

4 doses of 0.5 mL

Arm title	MenC (Group VII)
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Arm description:

Subjects received one dose of meningococcal C conjugate vaccine (Menjugate®; Men C) and routine vaccine at 2,3,4 months of age, one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation VII) and routine vaccine at 12 months of age. One dose of rMenB+OMV NZ and one dose of MenC at 13 months of age.

Arm type	Experimental
Investigational medicinal product name	4CMenB
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

two doses of 0.5 mL

Investigational medicinal product name	Prevenar
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

4 doses of 0.5 mL

Investigational medicinal product name	MenC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

five doses of 0.5 mL each

Investigational medicinal product name	Infanrix Hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

4 doses of 0.5 mL

Arm title	Par+B+OMV (Group VIII)
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Arm description:

Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation I) with paracetamol and routine vaccines at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.

Arm type	Experimental
Investigational medicinal product name	Prevenar
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details: 4 doses of 0.5 mL	
Investigational medicinal product name	Infanrix Hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details: 4 doses of 0.5 mL	
Investigational medicinal product name	MenC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: one dose of of 0.5 mL	
Investigational medicinal product name	Paracetamol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use
Dosage and administration details: 10-15 mg/Kg	
Investigational medicinal product name	4CMenB
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: four doses of 0.5 mL	

Number of subjects in period 2^[1]	B+OMV (Group I)	B+½ OMV (Group II)	B+1/4 OMV (Group III)
Started	155	163	169
Completed	152	161	164
Not completed	3	2	5
Adverse Event or Death	-	-	-
Consent withdrawn by subject	1	-	-
Administrative Reason	-	-	1
Lost to follow-up	2	2	4
Protocol deviation	-	-	-

Number of subjects in period 2^[1]	B (Group IV)	½ (B+OMV) (Group V)	PH2 B+OMV (Group VI)
Started	170	168	165

Completed	167	163	160
Not completed	3	5	5
Adverse Event or Death	-	-	-
Consent withdrawn by subject	1	-	-
Administrative Reason	-	1	1
Lost to follow-up	2	4	4
Protocol deviation	-	-	-

Number of subjects in period 2^[1]	MenC (Group VII)	Par+B+OMV (Group VIII)
Started	165	161
Completed	160	159
Not completed	5	2
Adverse Event or Death	1	-
Consent withdrawn by subject	-	2
Administrative Reason	-	-
Lost to follow-up	3	-
Protocol deviation	1	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: A total of 107 subjects (7% of enrolled subjects) who were enrolled before the second protocol amendment (that allowed participation in booster phase of the study) and were unwilling to participate in the booster phase were considered to have completed the study protocol after primary vaccination phase.

Baseline characteristics

Reporting groups

Reporting group title	B+OMV (Group I)
Reporting group description: Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation I) and routine vaccines at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.	
Reporting group title	B+½ OMV (Group II)
Reporting group description: Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation II) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.	
Reporting group title	B+1/4 OMV (Group III)
Reporting group description: Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation III) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.	
Reporting group title	B (Group IV)
Reporting group description: Subjects in this group received one dose of meningococcal B recombinant (rMenB) adsorbed vaccine (formulation IV) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.	
Reporting group title	½ (B+OMV) (Group V)
Reporting group description: Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation V) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.	
Reporting group title	PH2 B+OMV (Group VI)
Reporting group description: Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation VI) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.	
Reporting group title	MenC (Group VII)
Reporting group description: Subjects received one dose of meningococcal C conjugate vaccine (Menjugate®; Men C) and routine vaccine at 2,3,4 months of age, one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation VII) and routine vaccine at 12 months of age, one dose of rMenB+OMV NZ and one dose of MenC at 13 months of age.	
Reporting group title	Par+B+OMV (Group VIII)
Reporting group description: Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation I) with paracetamol and routine vaccines at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.	

Reporting group values	B+OMV (Group I)	B+½ OMV (Group II)	B+1/4 OMV (Group III)
Number of subjects	188	190	192
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months)			

Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: days arithmetic mean standard deviation	74 ± 10.6	74.7 ± 9.4	74.4 ± 9.7
Gender categorical Units: Subjects			
Female	88	91	82
Male	100	99	110

Reporting group values	B (Group IV)	½ (B+OMV) (Group V)	PH2 B+OMV (Group VI)
Number of subjects	188	191	188
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: days arithmetic mean standard deviation	75.3 ± 8.8	74.8 ± 9.3	74.6 ± 9
Gender categorical Units: Subjects			
Female	96	79	93
Male	92	112	95

Reporting group values	MenC (Group VII)	Par+B+OMV (Group VIII)	Total
Number of subjects	186	184	1507
Age categorical Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			0
Newborns (0-27 days)			0
Infants and toddlers (28 days-23 months)			0
Children (2-11 years)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0

85 years and over			0
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Age continuous			
Units: days			
arithmetic mean	74.9	74.4	
standard deviation	± 9.5	± 9	-
Gender categorical			
Units: Subjects			
Female	98	72	699
Male	88	112	808

End points

End points reporting groups

Reporting group title	B+OMV (Group I)
Reporting group description: Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation I) and routine vaccines at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.	
Reporting group title	B+½ OMV (Group II)
Reporting group description: Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation II) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.	
Reporting group title	B+1/4 OMV (Group III)
Reporting group description: Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation III) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.	
Reporting group title	B (Group IV)
Reporting group description: Subjects in this group received one dose of meningococcal B recombinant (rMenB) adsorbed vaccine (formulation IV) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.	
Reporting group title	½ (B+OMV) (Group V)
Reporting group description: Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation V) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.	
Reporting group title	PH2 B+OMV (Group VI)
Reporting group description: Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation VI) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.	
Reporting group title	MenC (Group VII)
Reporting group description: Subjects received one dose of meningococcal C conjugate vaccine (Menjugate®; Men C) and routine vaccine at 2,3,4 months of age, one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation VII) and routine vaccine at 12 months of age, one dose of rMenB+OMV NZ and one dose of MenC at 13 months of age.	
Reporting group title	Par+B+OMV (Group VIII)
Reporting group description: Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation I) with paracetamol and routine vaccines at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.	
Reporting group title	B+OMV (Group I)
Reporting group description: Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation I) and routine vaccines at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.	
Reporting group title	B+½ OMV (Group II)
Reporting group description: Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation II) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.	
Reporting group title	B+1/4 OMV (Group III)
Reporting group description: Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation III) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.	

months of age.

Reporting group title	B (Group IV)
Reporting group description:	
Subjects in this group received one dose of meningococcal B recombinant (rMenB) adsorbed vaccine (formulation IV) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.	
Reporting group title	½ (B+OMV) (Group V)
Reporting group description:	
Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation V) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.	
Reporting group title	PH2 B+OMV (Group VI)
Reporting group description:	
Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation VI) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.	
Reporting group title	MenC (Group VII)
Reporting group description:	
Subjects received one dose of meningococcal C conjugate vaccine (Menjugate®; Men C) and routine vaccine at 2,3,4 months of age, one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation VII) and routine vaccine at 12 months of age. One dose of rMenB+OMV NZ and one dose of MenC at 13 months of age.	
Reporting group title	Par+B+OMV (Group VIII)
Reporting group description:	
Subjects in this group received one dose of meningococcal B recombinant (rMenB+OMV NZ) adsorbed vaccine (formulation I) with paracetamol and routine vaccines at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age.	

Primary: Percentages of subjects with serum bactericidal activity (hSBA) ≥ 1:5 at 1 month after third vaccination

End point title	Percentages of subjects with serum bactericidal activity (hSBA) ≥ 1:5 at 1 month after third vaccination ^[1]
End point description:	
To assess the immunogenicity of seven different formulations of 4CMenB (groups I-VI and VIII) given to healthy infants at 2,3 and 4 months of age as measured by percentages of subjects with serum bactericidal activity (SBA) titer≥1:5 against 44/76-SL, 5/99 and NZ98/254 reference strains, at 1 month after the third vaccination.. The analysis was done on the Per Protocol Primary Population at one month after third injection.	
End point type	Primary
End point timeframe:	
At baseline (pre-vaccination) and 30 days after the third vaccination.	

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: There was no statistical null hypothesis associated with this immunogenicity objective.

End point values	B+OMV (Group I)	B+½ OMV (Group II)	B+1/4 OMV (Group III)	B (Group IV)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	171	174	171	174
Units: Percentages of Subjects				
number (confidence interval 95%)				
44/76-SL Bas (N=166,171,168,170,169,168,168,166)	5 (2 to 9)	2 (0 to 5)	4 (1 to 8)	4 (2 to 8)
44/76-SL > 3rd (N=170,170,166,166,169,167,165,167)	100 (98 to 100)	99 (97 to 100)	99 (97 to 100)	100 (98 to 100)

5/99 Baseline (N=162,162,161,161,166,166,161,157)	5 (2 to 9)	3 (1 to 7)	6 (3 to 10)	4 (2 to 9)
5/99 > 3rd (N=165,167,161,166,165,161,159,160)	99 (97 to 100)	100 (98 to 100)	99 (97 to 100)	100 (98 to 100)
NZ98/254 Basel (N=170,174,171,174,171,173,171,169)	1 (0.015 to 3)	0 (0 to 2)	1 (0.015 to 3)	1 (0.015 to 3)
NZ98/254 > 3rd (171,172,169,168,172,169,168,168)	78 (71 to 84)	67 (59 to 74)	56 (48 to 64)	1 (0.015 to 3)

End point values	½ (B+OMV) (Group V)	PH2 B+OMV (Group VI)	MenC (Group VII)	Par+B+OMV (Group VIII)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	172	173	171	169
Units: Percentages of Subjects				
number (confidence interval 95%)				
44/76-SL Bas (N=166,171,168,170,169,168,168,166)	4 (2 to 8)	4 (2 to 8)	2 (1 to 6)	3 (1 to 7)
44/76-SL > 3rd (N=170,170,166,166,169,167,165,167)	99 (97 to 100)	99 (96 to 100)	6 (3 to 11)	100 (98 to 100)
5/99 Baseline (N=162,162,161,161,166,166,161,157)	8 (5 to 14)	4 (2 to 8)	6 (3 to 10)	4 (1 to 8)
5/99 > 3rd (N=165,167,161,166,165,161,159,160)	100 (98 to 100)	99 (97 to 100)	3 (1 to 7)	99 (97 to 100)
NZ98/254 Basel (N=170,174,171,174,171,173,171,169)	1 (0 to 4)	1 (0 to 4)	2 (0 to 5)	1 (0.015 to 3)
NZ98/254 > 3rd (171,172,169,168,172,169,168,168)	62 (54 to 69)	81 (74 to 87)	2 (0 to 5)	74 (67 to 81)

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with fever ≥ 38.5 °C (rectal temperature) within 3 days (day 1-3) after first vaccination

End point title	Number of subjects with fever ≥ 38.5 °C (rectal temperature) within 3 days (day 1-3) after first vaccination ^[2]
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End point description:

To assess if any of six different formulations of vaccine groups (Group II to Group VI, Group VIII) reduced the incidence of fever ≥ 38.5 °C (rectal) occurring within three days (day 1-day3) following first vaccination. The analysis was done on the Safety Population.

End point type	Primary
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End point timeframe:

Day 1 to day 3 after first vaccination.

Notes:

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

Justification: All safety analyses were run in the safety population.

End point values	B+OMV (Group I)	B+½ OMV (Group II)	B+1/4 OMV (Group III)	B (Group IV)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	182	180	186	184
Units: Subjects				
fever ≥ 38.5 °C (rectal temperature)	94	91	74	24

End point values	½ (B+OMV) (Group V)	PH2 B+OMV (Group VI)	MenC (Group VII)	Par+B+OMV (Group VIII)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	182	180	177	179
Units: Subjects				
fever ≥ 38.5 °C (rectal temperature)	60	76	21	46

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Bactericidal Titers (GMTs), One Month After Third and Booster Vaccination

End point title	Geometric Mean Bactericidal Titers (GMTs), One Month After Third and Booster Vaccination
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End point description:

To assess the immune response of seven different formulations of meningococcal multi-component recombinant, adsorbed vaccine (rMenB+OMV NZ or rMenB (no OMV)) in healthy toddlers as measured by SBA geometric mean titers (GMTs) at:

1. One month after third vaccination.
2. One month after booster vaccination.

The analysis was done on the Per Protocol Primary and Booster populations.

End point type	Secondary
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End point timeframe:

At baseline (pre-vaccination), 30 days after the third vaccination, at booster Baseline and at booster vaccination.

End point values	B+OMV (Group I)	B+½ OMV (Group II)	B+1/4 OMV (Group III)	B (Group IV)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	171	174	171	174
Units: Titers				
geometric mean (confidence interval 95%)				
44/76-SL Base (N=166,171,168,170,169,168,168,166)	1.25 (1.14 to 1.37)	1.12 (1.03 to 1.23)	1.2 (1.1 to 1.32)	1.19 (1.08 to 1.3)
44/76-SL > 3 (N=170,170,166,166,169,167,165,167)	101 (90 to 113)	112 (101 to 126)	113 (101 to 126)	62 (56 to 70)
44/76-SL – Base Boost (N=69,78,74,78,71,71,74,70)	4.94 (3.76 to 6.5)	5.22 (4.03 to 6.76)	5.72 (4.41 to 7.42)	5.44 (4.19 to 7.06)

44/76-SL > Boost (N=65,73,70,75,76,71,75,63)	120 (95 to 150)	152 (122 to 189)	118 (95 to 146)	53 (43 to 66)
5/99 – Base (N=162,162,161,161,166,166,161,157)	1.18 (1.07 to 1.3)	1.09 (0.99 to 1.2)	1.12 (1.02 to 1.23)	1.13 (1.03 to 1.25)
5/99 > 3 (N=165,167,161,166,165,161,159,160)	396 (348 to 450)	503 (442 to 572)	534 (469 to 608)	389 (342 to 443)
5/99 Base Boost (N=71,76,80,72,77,78,70,71)	69 (53 to 88)	91 (71 to 116)	111 (87 to 141)	74 (57 to 94)
5/99 > Boost (N=73,77,79,72,76,74,69,76)	1950 (1573 to 2417)	1819 (1478 to 2238)	2238 (1820 to 2751)	730 (590 to 903)
NZ98/254 Base (N=170,174,171,174,171,173,171,169)	1.02 (0.99 to 1.06)	1.02 (0.99 to 1.05)	1.03 (1 to 1.06)	1.04 (1 to 1.07)
NZ98/254 > 3 (N=171,172,169,168,172,169,168,168)	10 (8.59 to 12)	7.81 (6.69 to 9.12)	5.74 (4.92 to 6.71)	1.05 (0.9 to 1.23)
NZ98/254 Bas Bst N=141,155,155,150,150,153,148,143	1.6 (1.43 to 1.8)	1.28 (1.15 to 1.43)	1.23 (1.1 to 1.37)	1.11 (0.99 to 1.24)
NZ98/254 >Boost N=138,152,150,149,152,146,147,140	20 (16 to 24)	18 (15 to 22)	11 (9.07 to 13)	1.67 (1.38 to 2.03)

End point values	½ (B+OMV) (Group V)	PH2 B+OMV (Group VI)	MenC (Group VII)	Par+B+OMV (Group VIII)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	172	173	171	169
Units: Titers				
geometric mean (confidence interval 95%)				
44/76-SL Base (N=166,171,168,170,169,168,168,166)	1.31 (1.19 to 1.43)	1.2 (1.09 to 1.31)	1.16 (1.09 to 1.25)	1.18 (1.08 to 1.3)
44/76-SL > 3 (N=170,170,166,166,169,167,165,167)	71 (64 to 80)	102 (92 to 114)	1.24 (1.11 to 1.39)	102 (91 to 115)
44/76-SL – Base Boost (N=69,78,74,78,71,71,74,70)	3.96 (3.02 to 5.18)	3.76 (2.87 to 4.94)	1.15 (1.03 to 1.29)	4.51 (3.43 to 5.95)
44/76-SL > Boost (N=65,73,70,75,76,71,75,63)	99 (79 to 122)	105 (84 to 131)	12 (10 to 16)	136 (107 to 172)
5/99 – Base (N=162,162,161,161,166,166,161,157)	1.3 (1.18 to 1.43)	1.16 (1.05 to 1.27)	1.21 (1.09 to 1.34)	1.07 (0.97 to 1.18)
5/99 > 3 (N=165,167,161,166,165,161,159,160)	316 (278 to 360)	371 (326 to 422)	1.15 (1.03 to 1.29)	455 (399 to 519)
5/99 Base Boost (N=71,76,80,72,77,78,70,71)	54 (42 to 68)	64 (50 to 81)	1.11 (0.95 to 1.29)	106 (82 to 136)
5/99 > Boost (N=73,77,79,72,76,74,69,76)	983 (801 to 1205)	1321 (1074 to 1624)	41 (29 to 57)	2182 (1769 to 2691)
NZ98/254 Base (N=170,174,171,174,171,173,171,169)	1.03 (1 to 1.06)	1.04 (1.01 to 1.08)	1.06 (1 to 1.13)	1.02 (0.99 to 1.05)
NZ98/254 > 3 (N=171,172,169,168,172,169,168,168)	6.66 (5.71 to 7.77)	11 (9.16 to 13)	1.05 (1.01 to 1.1)	8.48 (7.24 to 9.93)
NZ98/254 Bas Bst N=141,155,155,150,150,153,148,143	1.35 (1.21 to 1.5)	1.41 (1.26 to 1.57)	1.03 (1 to 1.06)	1.48 (1.32 to 1.66)
NZ98/254 >Boost N=138,152,150,149,152,146,147,140	14 (12 to 17)	20 (16 to 24)	2.2 (1.89 to 2.57)	20 (17 to 25)

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Bactericidal Titers, One Month After Primary and Booster Vaccination

End point title	Geometric Mean Bactericidal Titers, One Month After Primary and Booster Vaccination ^[3]
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End point description:

To compare the antibody response of meningococcal multi-component recombinant, adsorbed vaccine (formulation I vs. formulation VIII) and of routine infant vaccine given with or without prophylactic administration of paracetamol medication in healthy toddlers. The analysis was done on the Per Protocol population.

End point type	Secondary
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End point timeframe:

At Baseline (pre-vaccination), at 30 days after the third vaccination, at booster Baseline, at 30 days after booster vaccination.

Notes:

[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: There was no statistical null hypothesis associated with this immunogenicity objective.

End point values	B+OMV (Group I)	Par+B+OMV (Group VIII)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	171	169		
Units: Titers				
geometric mean (confidence interval 95%)				
44/76-SL Baseline (N=166,166)	1.25 (1.14 to 1.37)	1.18 (1.08 to 1.3)		
44/76-SL > 3rd (N=170,167)	101 (90 to 113)	102 (91 to 115)		
44/76-SL Baseline Booster (N=69,70)	4.94 (3.76 to 6.5)	4.51 (3.43 to 5.95)		
44/76-SL > Booster (N=65,63)	120 (95 to 150)	136 (107 to 172)		
5/99 Baseline (N=162,157)	1.18 (1.07 to 1.3)	1.07 (0.97 to 1.18)		
5/99 > 3rd (N=165,160)	396 (348 to 450)	455 (399 to 519)		
5/99 Baseline Booster (N=71,71)	69 (53 to 88)	106 (82 to 136)		
5/99 > Booster (N=73,76)	1950 (1573 to 2417)	2182 (1769 to 2691)		
NZ98/254 Baseline (N=170,169)	1.02 (0.99 to 1.06)	1.02 (0.99 to 1.05)		
NZ98/254 > 3rd (N=171,168)	10 (8.59 to 12)	8.48 (7.24 to 9.93)		
NZ98/254 Baseline Booster (N=141,143)	1.6 (1.43 to 1.8)	1.48 (1.32 to 1.66)		
NZ98/254 > Booster (N=138,140)	20 (16 to 24)	20 (17 to 25)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Ratios, One Month After Primary and Booster Vaccination

End point title	Geometric Mean Ratios, One Month After Primary and Booster Vaccination ^[4]
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End point description:

To compare the antibody response between meningococcal multi-component recombinant adsorbed vaccine (formulation I) and routine infant vaccine group along with meningococcal multi-component recombinant adsorbed vaccine with prophylactic administration of paracetamol medication as measured by Geometric Mean Ratios (GMRs).

The analysis was done on the Per Protocol population.

End point type	Secondary
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End point timeframe:

After the third and the booster vaccination.

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: There was no statistical null hypothesis associated with this immunogenicity objective.

End point values	B+OMV (Group I)	Par+B+OMV (Group VIII)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	162	160		
Units: Ratios				
geometric mean (confidence interval 95%)				
44/76-SL > 3rd (N=157,157)	80 (69 to 93)	84 (72 to 97)		
44/76-SL > Booster (N=59,56)	24 (18 to 31)	28 (21 to 36)		
5/99 > 3rd (N=152,142)	345 (292 to 408)	417 (350 to 497)		
5/99 > Booster (N=68,68)	27 (21 to 35)	20 (16 to 25)		
NZ98/254 > 3rd (N=162,160)	9.65 (8.19 to 11)	8.69 (7.36 to 10)		
NZ98/254 > Booster (N=129,127)	12 (10 to 15)	14 (11 to 17)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of Subjects With SBA titer $\geq 1:5$, Persistence of Bactericidal Antibodies at 12 Months of Age (Pre-fourth Dose)

End point title	Percentages of Subjects With SBA titer $\geq 1:5$, Persistence of Bactericidal Antibodies at 12 Months of Age (Pre-fourth Dose)
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End point description:

To assess the persistence of bactericidal antibodies at 12 months of age after primary vaccination - three doses of one of the seven different formulations of rMenB+OMV NZ or rMenB (no OMV) (Group I-VI and VIII) and rMenB+OMV NZ with paracetamol medication.

The analysis was done on the Per Protocol Booster population.

End point type	Secondary
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End point timeframe:

12 months (pre-fourth vaccination)

End point values	B+OMV (Group I)	B+½ OMV (Group II)	B+1/4 OMV (Group III)	B (Group IV)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	141	155	155	150
Units: Percentages of Subjects				
number (confidence interval 95%)				
44/76-SL Pre-Boost (N=69,78,74,78,71,71,74,70)	55 (43 to 67)	58 (46 to 69)	66 (54 to 77)	63 (51 to 74)
5/99 Pre-Boost (N=71,76,80,72,77,78,70,71)	97 (90 to 100)	100 (95 to 100)	100 (95 to 100)	97 (90 to 100)
NZ98/254 Pre-B (N=141,155,155,150,150,153,148,143)	12 (7 to 19)	6 (3 to 11)	5 (2 to 10)	3 (1 to 7)

End point values	½ (B+OMV) (Group V)	PH2 B+OMV (Group VI)	MenC (Group VII)	Par+B+OMV (Group VIII)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	150	153	148	143
Units: Percentages of Subjects				
number (confidence interval 95%)				
44/76-SL Pre-Boost (N=69,78,74,78,71,71,74,70)	45 (33 to 57)	44 (32 to 56)	4 (1 to 11)	47 (35 to 59)
5/99 Pre-Boost (N=71,76,80,72,77,78,70,71)	97 (91 to 100)	99 (93 to 100)	1 (0.036 to 8)	100 (95 to 100)
NZ98/254 Pre-B (N=141,155,155,150,150,153,148,143)	7 (3 to 12)	8 (4 to 13)	0 (0 to 2)	11 (7 to 18)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of Subjects With SBA titer ≥1:5, Persistence of Bactericidal Antibodies at 12 Months of Age (One Month-post Fourth Dose)

End point title	Percentages of Subjects With SBA titer ≥1:5, Persistence of Bactericidal Antibodies at 12 Months of Age (One Month-post Fourth Dose)
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End point description:

To assess if any of seven different formulations of rMenB+OMV NZ or rMenB (no OMV) vaccine (groups I-VI and VIII) induced sufficient immune response when given to healthy toddlers at 12 months of age, as measured by percentage of subjects with SBA titer ≥ 1:5, at 1 month after the fourth vaccination. The analysis was done on the Per Protocol Booster population.

End point type	Secondary
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End point timeframe:

1 month after fourth vaccination.

End point values	B+OMV (Group I)	B+½ OMV (Group II)	B+1/4 OMV (Group III)	B (Group IV)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	138	152	150	149
Units: Percentages of Subjects				
number (confidence interval 95%)				
44/76-SL > Booster (N=65,73,70,75,76,71,75,63)	100 (94 to 100)	100 (95 to 100)	100 (95 to 100)	97 (91 to 100)
5/99 > (N=73,77,79,72,76,74,69,76)	100 (95 to 100)	100 (95 to 100)	100 (95 to 100)	100 (95 to 100)
NZ98/254 > (N=138,152,150,149,152,146,147,140)	89 (83 to 94)	89 (83 to 93)	78 (71 to 84)	18 (12 to 25)

End point values	½ (B+OMV) (Group V)	PH2 B+OMV (Group VI)	MenC (Group VII)	Par+B+OMV (Group VIII)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	152	146	147	140
Units: Percentages of Subjects				
number (confidence interval 95%)				
44/76-SL > Booster (N=65,73,70,75,76,71,75,63)	100 (95 to 100)	99 (92 to 100)	84 (74 to 91)	100 (94 to 100)
5/99 > (N=73,77,79,72,76,74,69,76)	100 (95 to 100)	100 (95 to 100)	93 (84 to 98)	100 (95 to 100)
NZ98/254 > (N=138,152,150,149,152,146,147,140)	83 (76 to 89)	88 (82 to 93)	24 (18 to 32)	90 (84 to 94)

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Bactericidal Titers, After Primary and Booster Vaccinations

End point title	Geometric Mean Bactericidal Titers, After Primary and Booster Vaccinations ^[5]
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End point description:

To assess the induction of immunological memory of three doses of meningococcal multi-component recombinant, adsorbed vaccine by comparing the serum bactericidal antibodies Geometric Mean Bactericidal Titers (GMTs) response in healthy toddlers administered the fourth dose at 12 months of age to the response in meningococcal B vaccine naive toddlers (Group VII) receiving the first dose of meningococcal multi-component recombinant, adsorbed vaccine at 12 months of age. The analysis was done on the Per Protocol population.

End point type	Secondary
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End point timeframe:
at 13 months

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: There was no statistical null hypothesis associated with this immunogenicity objective.

End point values	B+OMV (Group I)	MenC (Group VII)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	138	147		
Units: Titers				
geometric mean (confidence interval 95%)				
44/76-SL > Booster (N=65,75)	120 (95 to 150)	12 (10 to 16)		
5/99 > Booster (N=73,69)	1950 (1573 to 2417)	41 (29 to 57)		
NZ98/254 > Booster (N=138, 147)	20 (16 to 24)	2.2 (1.89 to 2.57)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of Subjects With SBA titer $\geq 1:5$, First Dose of Meningococcal B Vaccine (One Month After Booster)

End point title	Percentages of Subjects With SBA titer $\geq 1:5$, First Dose of Meningococcal B Vaccine (One Month After Booster)
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End point description:

To assess the immune response of first dose of meningococcal mult-component recombinant, adsorbed vaccine given at 12 months of age to toddlers who previously received three doses of MenC-CRM197 vaccine as infants (group VII). The analysis was done on the Per Protocol population.

End point type	Secondary
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End point timeframe:

1 month after booster.

End point values	MenC (Group VII)			
Subject group type	Reporting group			
Number of subjects analysed	147			
Units: Percentages of Subjects				
number (confidence interval 95%)				
44/76-SL > Booster (N=75)	84 (74 to 91)			
5/99 > Booster (N=69)	93 (84 to 98)			
NZ98/254 > Booster (N=147)	24 (18 to 32)			

Statistical analyses

No statistical analyses for this end point

Secondary: Safety and Reactogenicity of Study Vaccines Within 7 Days After Second and Third Vaccination

End point title	Safety and Reactogenicity of Study Vaccines Within 7 Days
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End point description:

To assess if any of six different formulations of rMenB+OMV NZ or rMenB (no OMV) vaccine (Group II to VI, Group VIII) reduced the incidence of fever $\geq 38.5^{\circ}\text{C}$ (rectal) occurring within 3 days (day 1-3) following second and third vaccination and 7 days (day 1-7) following each vaccination as compared to rMenB+OMV NZ (Group I).

The analysis was performed on the safety population.

End point type

Secondary

End point timeframe:

Day 1 through day 7 after second and third vaccination.

End point values	B+OMV (Group I)	B+½ OMV (Group II)	B+1/4 OMV (Group III)	B (Group IV)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	182	180	186	184
Units: Subjects				
Second Vaccination (day 1-3)	90	82	76	35
3rd vac d 1-3 (N=181,179,185,183,181,180,177,179)	55	50	36	15
First Vaccination (day 1-7)	94	91	74	24
Second Vaccination (day 1-7)	90	82	77	36
3rd vac d 1-7 (N=181,179,185,183,181,180,177,179)	55	53	38	16
Booster d 1-7 (N=155,162,169,168,168,165,164,159)	81	86	64	43

End point values	½ (B+OMV) (Group V)	PH2 B+OMV (Group VI)	MenC (Group VII)	Par+B+OMV (Group VIII)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	182	180	177	179
Units: Subjects				
Second Vaccination (day 1-3)	74	89	30	33
3rd vac d 1-3 (N=181,179,185,183,181,180,177,179)	40	53	12	20
First Vaccination (day 1-7)	60	76	22	46
Second Vaccination (day 1-7)	74	90	30	35
3rd vac d 1-7 (N=181,179,185,183,181,180,177,179)	42	54	14	20
Booster d 1-7 (N=155,162,169,168,168,165,164,159)	78	68	84	58

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited local reactions within 7 days (day 1-7) after each vaccination

End point title

Number of subjects with solicited local reactions within 7 days

End point description:

To assess the safety and tolerability of each of seven different formulations of rMenB+OMV NZ or rMenB (no OMV) vaccine (group I to VI, group VIII) in terms of number of subjects reporting solicited local reactions within 7 days (day 1-7) after each vaccination. The analysis was performed on the safety population.

End point type

Secondary

End point timeframe:

Day 1 through day 7 after each vaccination.

End point values	B+OMV (Group I)	B+½ OMV (Group II)	B+1/4 OMV (Group III)	B (Group IV)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	182	180	186	184
Units: Subjects				
Any Local (First Vacc)	163	155	153	123
Injection Site Tenderness (First Vacc)	114	116	111	54
Injection Site Erythema (First Vacc)	108	99	94	53
Injection Site Induration (First Vacc)	101	98	85	48
Injection Site Swelling (First Vacc)	58	49	55	24
Any Local (Second Vacc)	156	156	155	126
Injection Site Tenderness (Second Vacc)	121	116	97	48
Injection Site Erythema (Second Vacc)	104	114	114	71
Injection Site Induration (Second Vacc)	103	105	97	63
Injection Site Swelling (Second Vacc)	64	61	54	34
Any Local (3rd N=181,179,185,183,181,180,177,179)	151	147	141	122
Injection Site Tenderness (Third Vacc)	102	98	78	47
Injection Site Erythema (Third Vacc)	110	106	112	72
Injection Site Induration (Third Vacc)	97	92	92	62
Injection Site Swelling (Third Vacc)	56	56	46	35
Any Local Boost N=155,162,169,168,168,165,162,159	131	132	149	113
Injection Site Tenderness (Booster Vacc)	116	107	120	77
Injection Site Erythema (Booster Vacc)	90	101	116	67
Injection Site Induration (Booster Vacc)	73	83	95	56
Injection Site Swelling (Booster Vacc)	55	59	69	31

End point values	½ (B+OMV) (Group V)	PH2 B+OMV (Group VI)	MenC (Group VII)	Par+B+OMV (Group VIII)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	182	180	177	179
Units: Subjects				
Any Local (First Vacc)	141	157	127	137
Injection Site Tenderness (First Vacc)	97	121	48	79
Injection Site Erythema (First Vacc)	77	106	45	73
Injection Site Induration (First Vacc)	86	84	25	82
Injection Site Swelling (First Vacc)	48	60	15	41

Any Local (Second Vacc)	132	156	118	140
Injection Site Tenderness (Second Vacc)	88	116	47	85
Injection Site Erythema (Second Vacc)	90	104	44	94
Injection Site Induration (Second Vacc)	83	94	38	79
Injection Site Swelling (Second Vacc)	50	58	21	52
Any Local (3rd N=181,179,185,183,181,180,177,179)	130	152	113	128
Injection Site Tenderness (Third Vacc)	77	111	42	66
Injection Site Erythema (Third Vacc)	94	101	63	91
Injection Site Induration (Third Vacc)	79	89	55	80
Injection Site Swelling (Third Vacc)	45	58	29	47
Any Local Boost N=155,162,169,168,168,165,162,159	127	130	133	121
Injection Site Tenderness (Booster Vacc)	106	112	108	92
Injection Site Erythema (Booster Vacc)	80	85	93	81
Injection Site Induration (Booster Vacc)	66	73	62	60
Injection Site Swelling (Booster Vacc)	47	52	39	47

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited systemic reactions within 7 days (day 1-7) after each vaccination

End point title	Number of subjects with solicited systemic reactions within 7 days (day 1-7) after each vaccination
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End point description:

To assess the safety and tolerability of each of seven different formulations of rMenB+OMV NZ or rMenB (no OMV) vaccine (group I to VI, group VIII) in terms of number of subjects reporting solicited systemic reactions within 7 days (day 1-7) after each vaccination. The analysis was performed on the safety population.

End point type	Secondary
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End point timeframe:

Day 1 through day 7 after each vaccination.

End point values	B+OMV (Group I)	B+½ OMV (Group II)	B+1/4 OMV (Group III)	B (Group IV)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	182	180	186	184
Units: Subjects				
Any Systemic (First Vacc)	167	173	175	152
Change Eat. Habits (First Vacc)	76	87	84	52
Sleepiness (First Vacc)	120	131	119	96
Vomiting (First Vacc)	24	18	25	15
Diarrhea (First Vacc)	57	55	54	31
Irritability (First Vacc)	128	124	128	99
Unus Crying (First Vacc)	95	101	105	61
Rash (First Vacc)	6	5	5	7

Fever ($\geq 38.5^{\circ}\text{C}$) (First Vacc)	94	91	74	24
Antipyr. Med. Used (First Vacc)	102	94	92	37
Any Systemic (Second Vacc)	168	158	166	144
Change Eat. Habits (Second Vacc)	62	55	58	53
Sleepiness (Second Vacc)	105	100	102	85
Vomiting (Second Vacc)	18	18	14	15
Diarrhea (Second Vacc)	43	41	47	40
Irritability (Second Vacc)	130	121	124	94
Unus Crying (Second Vacc)	90	90	84	70
Rash (Second Vacc)	4	9	4	5
Fever ($\geq 38.5^{\circ}\text{C}$) (Second Vacc)	90	82	77	36
Antipyr. Med. Used (Second Vacc)	100	94	83	40
Any Syst (3rd N=181,179,185,182,181,180,177,179)	146	131	132	122
Change Eat. Habits (Third Vacc)	49	50	42	37
Sleepiness (Third Vacc)	75	67	82	64
Vomiting (Third Vacc)	8	18	15	12
Diarrhea (Third Vacc)	33	29	39	31
Irritability (Third Vacc)	115	97	93	74
Unus Crying (Third Vacc)	76	82	62	47
Rash (Third Vacc)	1	6	4	2
Fever ($\geq 38.5^{\circ}\text{C}$) (Third Vacc)	55	53	38	16
Antipyr. Med. Used (Third Vacc)	66	60	51	26
Any Syst(Boos N=155,162,169,169,168,165,164,159)	143	144	139	118
Change Eat. Habits (Booster Vacc)	74	77	79	52
Sleepiness (Booster Vacc)	76	90	90	63
Vomiting (Booster Vacc)	6	11	7	7
Diarrhea (Booster Vacc)	30	34	36	43
Irritability (Booster Vacc)	116	111	112	86
Unus Crying (Booster Vacc)	74	64	69	46
Rash (Booster Vacc)	5	5	8	2
Fever ($\geq 38.5^{\circ}\text{C}$) (Booster Vacc)	81	86	64	43
Antipyr. Med. Used (Booster Vacc)	84	82	83	42

End point values	$\frac{1}{2}$ (B+OMV) (Group V)	PH2 B+OMV (Group VI)	MenC (Group VII)	Par+B+OMV (Group VIII)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	182	180	177	179
Units: Subjects				
Any Systemic (First Vacc)	162	171	136	150
Change Eat. Habits (First Vacc)	84	90	41	66
Sleepiness (First Vacc)	117	119	92	116
Vomiting (First Vacc)	22	26	17	22
Diarrhea (First Vacc)	41	49	45	41
Irritability (First Vacc)	131	131	79	97
Unus Crying (First Vacc)	96	108	63	74
Rash (First Vacc)	10	10	4	5
Fever ($\geq 38.5^{\circ}\text{C}$) (First Vacc)	60	76	22	46
Antipyr. Med. Used (First Vacc)	74	95	32	166

Any Systemic (Second Vacc)	156	158	126	147
Change Eat. Habits (Second Vacc)	60	80	33	54
Sleepiness (Second Vacc)	92	109	75	84
Vomiting (Second Vacc)	17	20	14	20
Diarrhea (Second Vacc)	39	47	39	40
Irritability (Second Vacc)	117	126	82	99
Unus Crying (Second Vacc)	83	99	45	71
Rash (Second Vacc)	7	4	5	5
Fever ($\geq 38.5^{\circ}\text{C}$) (Second Vacc)	74	90	30	35
Antipyr. Med. Used (Second Vacc)	79	105	39	163
Any Syst (3rd N=181,179,185,182,181,180,177,179)	141	151	106	127
Change Eat. Habits (Third Vacc)	45	60	22	48
Sleepiness (Third Vacc)	77	79	52	75
Vomiting (Third Vacc)	12	13	11	20
Diarrhea (Third Vacc)	34	40	19	32
Irritability (Third Vacc)	104	115	76	84
Unus Crying (Third Vacc)	69	100	38	47
Rash (Third Vacc)	8	10	6	6
Fever ($\geq 38.5^{\circ}\text{C}$) (Third Vacc)	42	54	14	20
Antipyr. Med. Used (Third Vacc)	49	63	20	153
Any Syst(Boos N=155,162,169,169,168,165,164,159)	141	142	142	137
Change Eat. Habits (Booster Vacc)	70	80	59	66
Sleepiness (Booster Vacc)	86	88	85	80
Vomiting (Booster Vacc)	10	9	9	20
Diarrhea (Booster Vacc)	32	30	26	30
Irritability (Booster Vacc)	116	115	117	96
Unus Crying (Booster Vacc)	71	82	73	50
Rash (Booster Vacc)	8	4	6	5
Fever ($\geq 38.5^{\circ}\text{C}$) (Booster Vacc)	78	68	84	58
Antipyr. Med. Used (Booster Vacc)	75	80	92	128

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with unsolicited Adverse Events within 7 days (day 1-7) after each vaccination

End point title	Number of subjects with unsolicited Adverse Events within 7 days (day 1-7) after each vaccination
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End point description:

To assess the safety and tolerability of each of seven different formulations of rMenB+OMV NZ or rMenB (no OMV) vaccine (group I to VI, group VIII) in terms of number of subjects reporting unsolicited Adverse Events (AEs), serious adverse events (SAEs), medically attended AEs, AEs leading to premature withdrawal (throughout the study period) within 7 days (day 1-7) after each vaccination. The analysis was performed on the safety population.

End point type	Secondary
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End point timeframe:

Day 1 through day 7 after each vaccination.

End point values	B+OMV (Group I)	B+½ OMV (Group II)	B+1/4 OMV (Group III)	B (Group IV)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	184	184	189	187
Units: Subjects				
Any AE (Day 1 to 7) (First Vacc)	55	52	51	33
At least Possibly related AE (First Vacc)	48	48	43	30
Any SAE (First Vacc)	0	1	0	0
Any AE D1-7 2nd N=182,181,186,184,183,180,178,180	55	53	50	41
At least Possibly related AE (Second Vacc)	49	45	45	36
Any SAE (Second Vacc)	1	0	1	0
Any AE D1-7 3rd N=182,181,186,184,182,180,177,179	40	59	49	35
At least Possibly related AE (Third Vacc)	34	52	45	29
Any SAE (Third Vacc)	2	0	2	0
Any AE D 1-7Boos N=155,163,169,169,168,165,165,161	35	46	56	35
At least Possibly related AE (Booster Vacc)	28	41	48	23
Any SAE (Booster Vacc)	0	1	2	0

End point values	½ (B+OMV) (Group V)	PH2 B+OMV (Group VI)	MenC (Group VII)	Par+B+OMV (Group VIII)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	187	185	184	183
Units: Subjects				
Any AE (Day 1 to 7) (First Vacc)	35	39	27	42
At least Possibly related AE (First Vacc)	27	34	22	36
Any SAE (First Vacc)	0	1	0	1
Any AE D1-7 2nd N=182,181,186,184,183,180,178,180	36	47	28	45
At least Possibly related AE (Second Vacc)	33	41	26	39
Any SAE (Second Vacc)	1	0	0	0
Any AE D1-7 3rd N=182,181,186,184,182,180,177,179	31	45	35	39
At least Possibly related AE (Third Vacc)	23	37	29	36
Any SAE (Third Vacc)	1	0	0	0
Any AE D 1-7Boos N=155,163,169,169,168,165,165,161	29	30	37	30
At least Possibly related AE (Booster Vacc)	23	26	30	25
Any SAE (Booster Vacc)	3	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with Severe Adverse Events and Adverse Events necessitating a medical office or Emergency Room (ER) visit and/or resulting in premature withdrawal of the subject from the study, throughout the study period

End point title	Number of subjects with Severe Adverse Events and Adverse Events necessitating a medical office or Emergency Room (ER) visit and/or resulting in premature withdrawal of the subject from the study, throughout the study period
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End point description:

To assess the safety and tolerability of each of seven different formulations of rMenB+OMV NZ or rMenB (no OMV) vaccine (group I to VI, group VIII) in terms of number of subjects reporting Severe Adverse Events (SAEs) and Adverse Events (AEs) necessitating a medical office or Emergency Room (ER) visit and/or resulting in premature withdrawal of the subject from the study, throughout the study period. The analysis was performed on the safety population.

End point type	Secondary
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End point timeframe:

Overall study period.

End point values	B+OMV (Group I)	B+½ OMV (Group II)	B+1/4 OMV (Group III)	B (Group IV)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	184	184	189	187
Units: Subjects				
AE Leading to Premature Withdrawal - Primary Vacc	0	2	2	0
Treatment Emergent SAEs - Primary Vacc	16	20	12	20
Tr E SAE Boost (N=155,163,169,169,168,165,165,161)	14	7	12	5

End point values	½ (B+OMV) (Group V)	PH2 B+OMV (Group VI)	MenC (Group VII)	Par+B+OMV (Group VIII)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	187	185	184	183
Units: Subjects				
AE Leading to Premature Withdrawal - Primary Vacc	0	1	2	1
Treatment Emergent SAEs - Primary Vacc	13	16	11	15
Tr E SAE Boost (N=155,163,169,169,168,165,165,161)	15	9	9	16

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with local and systemic reactions within 7 days (day 1-7) after second rMenB+OMV NX vaccination in MenC group

End point title	Number of subjects with local and systemic reactions within 7 days (day 1-7) after second rMenB+OMV NX vaccination in MenC group ^[6]
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End point description:

To assess the safety and tolerability of two doses of rMenB+OMV NZ vaccine (Group VII) given at 12 and 13 months of age to toddlers who previously received three doses of Menjugate as infants. The analysis was performed on the safety population.

End point type	Secondary
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End point timeframe:

Day 1 through day 7 at 13 months age.

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: All safety analyses were run in the safety population.

End point values	MenC (Group VII)			
Subject group type	Reporting group			
Number of subjects analysed	156			
Units: Subjects				
Injection Site Tenderness	92			
Injection Site Erythema	84			
Injection Site Induration	59			
Injection Site Swelling	35			
Change Eat. Habits (N=155)	43			
Sleepiness	57			
Vomiting	8			
Diarrhea	18			
Irritability	75			
Unus Crying	37			
Rash	4			
Fever (≥ 38.5°C) (N=158)	35			
Antipyr. Med. Used (N=157)	47			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All solicited AEs and unsolicited AEs were collected from Day 1 to Day 7; serious adverse events (SAEs), medically attended AEs, AEs leading to premature withdrawal were collected during the overall study period.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	14.1

Reporting groups

Reporting group title	B+OMV (Group I)
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Reporting group description:

Subjects in this group received one dose of meningococcal B recombinant (rMenB) adsorbed vaccine (formulation I) and routine vaccines at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age. Group defined to be applicable Prior to Booster Phase for AEs reporting.

Reporting group title	B+½ OMV (Group II)
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Reporting group description:

Subjects in this group received one dose of meningococcal B recombinant (rMenB) adsorbed vaccine (formulation II) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age. Group defined to be applicable Prior to Booster Phase for AEs reporting.

Reporting group title	B+1/4 OMV (Group III)
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Reporting group description:

Subjects in this group received one dose of meningococcal B recombinant (rMenB) adsorbed vaccine (formulation III) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age. Group defined to be applicable Prior to Booster Phase for AEs reporting.

Reporting group title	B (Group IV)
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Reporting group description:

Subjects in this group received one dose of meningococcal B recombinant (rMenB) adsorbed vaccine (formulation IV) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age. Group defined to be applicable Prior to Booster Phase for AEs reporting.

Reporting group title	½ (B+OMV) (Group V)
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Reporting group description:

Subjects in this group received one dose of meningococcal B recombinant (rMenB) adsorbed vaccine (formulation V) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age. Group defined to be applicable Prior to Booster Phase for AEs reporting.

Reporting group title	PH2 B+OMV (Group VI)
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Reporting group description:

Subjects in this group received one dose of meningococcal B recombinant (rMenB) adsorbed vaccine (formulation VI) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age. Group defined to be applicable Prior to Booster Phase for AEs reporting.

Reporting group title	MenC (Group VII)
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Reporting group description:

Subjects received one dose of meningococcal C conjugate vaccine (Menjugate®; Men C) and routine vaccine at 2,3,4 months of age and one dose of meningococcal B recombinant (rMenB) adsorbed vaccine (formulation VII) and routine vaccine at 12 months of age. One dose of MenC at 13 months of age. Group defined to be applicable Prior to Booster Phase for AEs reporting.

Reporting group title	183Par+B+OMV (Group VIII)
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Reporting group description:

Subjects in this group received one dose of meningococcal B recombinant (rMenB) adsorbed vaccine (formulation I) with paracetamol and routine vaccines at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age. Group defined to be applicable Prior to Booster Phase for AEs reporting.

Reporting group title	B+OMV (Group I) Booster Phase
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Reporting group description:

Subjects in this group received one dose of meningococcal B recombinant (rMenB) adsorbed vaccine

(formulation I) and routine vaccines at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age. It includes Booster Phase.

Reporting group title	B+½ OMV (Group II) Booster Phase
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Reporting group description:

Subjects in this group received one dose of meningococcal B recombinant (rMenB) adsorbed vaccine (formulation II) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age. It includes Booster Phase.

Reporting group title	B+1/4 OMV (Group III) Booster Phase
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Reporting group description:

Subjects in this group received one dose of meningococcal B recombinant (rMenB) adsorbed vaccine (formulation III) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age. Group defined to include Booster Phase.

Reporting group title	B (Group IV) Booster Phase
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Reporting group description:

Subjects in this group received one dose of meningococcal B recombinant (rMenB) adsorbed vaccine (formulation IV) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age. Group defined to include Booster Phase.

Reporting group title	½ (B+OMV) (Group V) Booster Phase
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Reporting group description:

Subjects in this group received one dose of meningococcal B recombinant (rMenB) adsorbed vaccine (formulation V) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age. Group defined to include Booster Phase.

Reporting group title	PH2 B+OMV (Group VI) Booster Phase
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Reporting group description:

Subjects in this group received one dose of meningococcal B recombinant (rMenB) adsorbed vaccine (formulation VI) and routine vaccine at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age. Group defined to include Booster Phase.

Reporting group title	MenC (Group VII) Booster Phase
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Reporting group description:

Subjects received one dose of meningococcal C conjugate vaccine (Menjugate®; Men C) and routine vaccine at 2,3,4 months of age and one dose of meningococcal B recombinant (rMenB) adsorbed vaccine (formulation VII) and routine vaccine at 12 months of age. One dose of MenC at 13 months of age. Group defined to include Booster Phase.

Reporting group title	Par+B+OMV (Group VIII) Booster Phase
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Reporting group description:

Subjects in this group received one dose of meningococcal B recombinant (rMenB) adsorbed vaccine (formulation I) with paracetamol and routine vaccines at 2,3,4,12 months of age and MenC-CRM197 at 13 months of age. Group defined to include Booster Phase.

Serious adverse events	B+OMV (Group I)	B+½ OMV (Group II)	B+1/4 OMV (Group III)
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 184 (8.70%)	20 / 184 (10.87%)	12 / 189 (6.35%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Fibroma			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Neoplasm			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Cleft palate repair			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 184 (0.54%)	0 / 184 (0.00%)	0 / 189 (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
Injection site erythema			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Milk allergy			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 184 (0.54%)	0 / 184 (0.00%)	1 / 189 (0.53%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			

subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenoidal hypertrophy			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Acoustic Stimulation Tests			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 184 (0.54%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Bone fissure			
subjects affected / exposed	0 / 184 (0.00%)	1 / 184 (0.54%)	0 / 189 (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
Concussion			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 184 (0.00%)	1 / 184 (0.54%)	0 / 189 (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
Foreign body aspiration			

subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	1 / 184 (0.54%)	0 / 184 (0.00%)	0 / 189 (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
Joint dislocation			
subjects affected / exposed	0 / 184 (0.00%)	1 / 184 (0.54%)	0 / 189 (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
Road traffic accident			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental exposure to product			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Congenital megacolon			

subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cryptorchism			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phimosis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Pulmonary valve stenosis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	1 / 184 (0.54%)	1 / 184 (0.54%)	0 / 189 (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
Guillain-Barre syndrome			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotonia			
subjects affected / exposed	0 / 184 (0.00%)	1 / 184 (0.54%)	0 / 189 (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
Myoclonic epilepsy			
subjects affected / exposed	1 / 184 (0.54%)	0 / 184 (0.00%)	0 / 189 (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
Partial seizures			

subjects affected / exposed	0 / 184 (0.00%)	1 / 184 (0.54%)	0 / 189 (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
VIth nerve paralysis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 184 (0.00%)	1 / 184 (0.54%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Aphthous stomatitis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 184 (0.54%)	0 / 189 (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
Enteritis			

subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	1 / 189 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis haemorrhagic			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	1 / 189 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	1 / 184 (0.54%)	0 / 184 (0.00%)	0 / 189 (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
Vomiting			
subjects affected / exposed	0 / 184 (0.00%)	1 / 184 (0.54%)	1 / 189 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Angioedema			

subjects affected / exposed	0 / 184 (0.00%)	1 / 184 (0.54%)	0 / 189 (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
Psoriasis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Acarodermatitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial pyelonephritis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	1 / 184 (0.54%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	3 / 184 (1.63%)	2 / 184 (1.09%)	4 / 189 (2.12%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	1 / 184 (0.54%)	0 / 184 (0.00%)	0 / 189 (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
Corona virus infection			

subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			
subjects affected / exposed	0 / 184 (0.00%)	1 / 184 (0.54%)	0 / 189 (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
Exanthema subitum			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	2 / 189 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 184 (0.54%)	2 / 184 (1.09%)	1 / 189 (0.53%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 184 (0.00%)	1 / 184 (0.54%)	0 / 189 (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
Laryngitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	1 / 189 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			

subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 184 (0.54%)	0 / 189 (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
Oral herpes			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 184 (0.00%)	3 / 184 (1.63%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 184 (0.00%)	1 / 184 (0.54%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	1 / 184 (0.54%)	0 / 184 (0.00%)	0 / 189 (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
Pyelonephritis			

subjects affected / exposed	0 / 184 (0.00%)	1 / 184 (0.54%)	1 / 189 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	1 / 189 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis			
subjects affected / exposed	1 / 184 (0.54%)	0 / 184 (0.00%)	0 / 189 (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
Rhinovirus infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	1 / 189 (0.53%)
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 respiratory tract infection			
subjects affected / exposed	0 / 184 (0.00%)	1 / 184 (0.54%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	1 / 184 (0.54%)	0 / 184 (0.00%)	1 / 189 (0.53%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 184 (0.00%)	1 / 184 (0.54%)	0 / 189 (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 tonsillitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bullous impetigo			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			

subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal abscess			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral myocarditis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 184 (0.00%)	0 / 184 (0.00%)	0 / 189 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	1 / 184 (0.54%)	0 / 184 (0.00%)	0 / 189 (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
Ketosis			
subjects affected / exposed	1 / 184 (0.54%)	0 / 184 (0.00%)	0 / 189 (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
Weight gain poor			

subjects affected / exposed	0 / 184 (0.00%)	1 / 184 (0.54%)	1 / 189 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	B (Group IV)	½ (B+OMV) (Group V)	PH2 B+OMV (Group VI)
Total subjects affected by serious adverse events			
subjects affected / exposed	20 / 187 (10.70%)	13 / 187 (6.95%)	16 / 185 (8.65%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Fibroma			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Cleft palate repair			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 187 (0.53%)	0 / 187 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site erythema			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Milk allergy			

subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 187 (0.53%)	1 / 187 (0.53%)	0 / 185 (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
Dyspnoea			
subjects affected / exposed	0 / 187 (0.00%)	1 / 187 (0.53%)	0 / 185 (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
Respiratory distress			
subjects affected / exposed	0 / 187 (0.00%)	1 / 187 (0.53%)	0 / 185 (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
Adenoidal hypertrophy			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Acoustic Stimulation Tests			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Bone fissure			

subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	1 / 187 (0.53%)	0 / 187 (0.00%)	0 / 185 (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	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body aspiration			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 187 (0.00%)	1 / 187 (0.53%)	0 / 185 (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
Joint dislocation			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			

subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental exposure to product			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Congenital megacolon			
subjects affected / exposed	1 / 187 (0.53%)	0 / 187 (0.00%)	0 / 185 (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	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phimosis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Pulmonary valve stenosis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Guillain-Barre syndrome			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotonia			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myoclonic epilepsy			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIth nerve paralysis			
subjects affected / exposed	1 / 187 (0.53%)	0 / 187 (0.00%)	0 / 185 (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
Somnolence			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	1 / 187 (0.53%)	0 / 187 (0.00%)	0 / 185 (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
Anaemia			

subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Aphthous stomatitis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis haemorrhagic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 187 (0.00%)	1 / 187 (0.53%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriasis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Acarodermatitis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial pyelonephritis			
subjects affected / exposed	1 / 187 (0.53%)	0 / 187 (0.00%)	0 / 185 (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
Bronchiolitis			

subjects affected / exposed	0 / 187 (0.00%)	1 / 187 (0.53%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	4 / 187 (2.14%)	1 / 187 (0.53%)	2 / 185 (1.08%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	1 / 187 (0.53%)	0 / 187 (0.00%)	0 / 185 (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
Corona virus infection			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			
subjects affected / exposed	0 / 187 (0.00%)	1 / 187 (0.53%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	3 / 187 (1.60%)	1 / 187 (0.53%)	3 / 185 (1.62%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	1 / 187 (0.53%)	1 / 187 (0.53%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			

subjects affected / exposed	1 / 187 (0.53%)	1 / 187 (0.53%)	0 / 185 (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
Infection			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	1 / 187 (0.53%)	0 / 187 (0.00%)	3 / 185 (1.62%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral herpes			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 187 (0.00%)	1 / 187 (0.53%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	1 / 187 (0.53%)	0 / 187 (0.00%)	0 / 185 (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
Pyelonephritis acute			
subjects affected / exposed	0 / 187 (0.00%)	2 / 187 (1.07%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 187 (0.00%)	1 / 187 (0.53%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 187 (0.53%)	1 / 187 (0.53%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	2 / 187 (1.07%)	1 / 187 (0.53%)	0 / 185 (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
Acute tonsillitis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bullous impetigo			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			

subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear infection			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal abscess			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchitis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheitis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral myocarditis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	1 / 187 (0.53%)	1 / 187 (0.53%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ketosis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight gain poor			
subjects affected / exposed	0 / 187 (0.00%)	0 / 187 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	MenC (Group VII)	183Par+B+OMV (Group VIII)	B+OMV (Group I) Booster Phase
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 184 (5.98%)	15 / 183 (8.20%)	14 / 155 (9.03%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Fibroma			
subjects affected / exposed	1 / 184 (0.54%)	0 / 183 (0.00%)	0 / 155 (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
Neoplasm			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Cleft palate repair			

subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	1 / 155 (0.65%)
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			
Pyrexia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site erythema			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Milk allergy			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenoidal hypertrophy			

subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Acoustic Stimulation Tests			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Bone fissure			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 184 (0.00%)	1 / 183 (0.55%)	0 / 155 (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
Fall			
subjects affected / exposed	0 / 184 (0.00%)	2 / 183 (1.09%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body aspiration			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			

subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 184 (0.00%)	1 / 183 (0.55%)	0 / 155 (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
Thermal burn			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	1 / 155 (0.65%)
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	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental exposure to product			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	1 / 155 (0.65%)
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			
Congenital megacolon			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cryptorchism			

subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phimosi			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Pulmonary valve stenosis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome			
subjects affected / exposed	1 / 184 (0.54%)	0 / 183 (0.00%)	0 / 155 (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
Hypotonia			
subjects affected / exposed	0 / 184 (0.00%)	1 / 183 (0.55%)	0 / 155 (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
Myoclonic epilepsy			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIth nerve paralysis			

subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Aphthous stomatitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis haemorrhagic			

subjects affected / exposed	0 / 184 (0.00%)	1 / 183 (0.55%)	0 / 155 (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
Gastritis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 184 (0.00%)	1 / 183 (0.55%)	0 / 155 (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
Inguinal hernia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriasis			

subjects affected / exposed	1 / 184 (0.54%)	0 / 183 (0.00%)	0 / 155 (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
Rash			
subjects affected / exposed	1 / 184 (0.54%)	0 / 183 (0.00%)	0 / 155 (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
Infections and infestations			
Acarodermatitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial pyelonephritis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	2 / 184 (1.09%)	1 / 183 (0.55%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	1 / 184 (0.54%)	2 / 183 (1.09%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Corona virus infection			
subjects affected / exposed	0 / 184 (0.00%)	1 / 183 (0.55%)	0 / 155 (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
Cytomegalovirus infection			

subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 184 (0.54%)	1 / 183 (0.55%)	2 / 155 (1.29%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 184 (0.00%)	1 / 183 (0.55%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 183 (0.55%)	0 / 155 (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
Oral candidiasis			

subjects affected / exposed	1 / 184 (0.54%)	0 / 183 (0.00%)	0 / 155 (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	1 / 184 (0.54%)	0 / 183 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	1 / 184 (0.54%)	0 / 183 (0.00%)	0 / 155 (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
Pharyngitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 184 (0.54%)	1 / 183 (0.55%)	0 / 155 (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 respiratory syncytial viral			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	2 / 184 (1.09%)	1 / 183 (0.55%)	0 / 155 (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
Pyelonephritis acute			

subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 184 (0.00%)	1 / 183 (0.55%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 184 (0.00%)	1 / 183 (0.55%)	0 / 155 (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
Sepsis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	1 / 184 (0.54%)	0 / 183 (0.00%)	0 / 155 (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
Tonsillitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			

subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 184 (0.00%)	1 / 183 (0.55%)	0 / 155 (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 tonsillitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bullous impetigo			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal abscess			

subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	1 / 155 (0.65%)
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 syncytial virus bronchitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral myocarditis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 184 (0.00%)	1 / 183 (0.55%)	0 / 155 (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
Dehydration			
subjects affected / exposed	1 / 184 (0.54%)	0 / 183 (0.00%)	0 / 155 (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
Ketosis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight gain poor			
subjects affected / exposed	0 / 184 (0.00%)	0 / 183 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	B+½ OMV (Group	B+1/4 OMV (Group	B (Group IV)
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	II) Booster Phase	III) Booster Phase	Booster Phase
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 163 (4.29%)	12 / 169 (7.10%)	5 / 169 (2.96%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Fibroma			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Cleft palate repair			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site erythema			
subjects affected / exposed	0 / 163 (0.00%)	1 / 169 (0.59%)	0 / 169 (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
Immune system disorders			
Milk allergy			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

Asthma	subjects affected / exposed	1 / 163 (0.61%)	0 / 169 (0.00%)	0 / 169 (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
Dyspnoea	subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress	subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenoidal hypertrophy	subjects affected / exposed	1 / 163 (0.61%)	0 / 169 (0.00%)	0 / 169 (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
Psychiatric disorders				
Affective disorder	subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations				
Acoustic Stimulation Tests alternative dictionary used: MedDRA 17.1	subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications				
Bone fissure	subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion				

subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 163 (0.00%)	2 / 169 (1.18%)	2 / 169 (1.18%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body aspiration			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 163 (0.00%)	1 / 169 (0.59%)	0 / 169 (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
Joint dislocation			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 163 (0.00%)	1 / 169 (0.59%)	0 / 169 (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
Toxicity to various agents			

subjects affected / exposed	0 / 163 (0.00%)	1 / 169 (0.59%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental exposure to product			
subjects affected / exposed	0 / 163 (0.00%)	1 / 169 (0.59%)	0 / 169 (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
Congenital, familial and genetic disorders			
Congenital megacolon			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cryptorchism			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phimosis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Pulmonary valve stenosis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	1 / 163 (0.61%)	0 / 169 (0.00%)	1 / 169 (0.59%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hypotonia			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myoclonic epilepsy			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
With nerve paralysis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis			

subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Aphthous stomatitis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis haemorrhagic			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			

subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriasis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Acarodermatitis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial pyelonephritis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			

subjects affected / exposed	1 / 163 (0.61%)	2 / 169 (1.18%)	0 / 169 (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
Bronchopneumonia			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Corona virus infection			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	2 / 163 (1.23%)	1 / 169 (0.59%)	1 / 169 (0.59%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	1 / 163 (0.61%)	2 / 169 (1.18%)	0 / 169 (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
Gastroenteritis viral			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			

subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	0 / 163 (0.00%)	1 / 169 (0.59%)	3 / 169 (1.78%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral herpes			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			

subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			

subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute tonsillitis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bullous impetigo			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 163 (0.00%)	1 / 169 (0.59%)	0 / 169 (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
Device related sepsis			

subjects affected / exposed	0 / 163 (0.00%)	1 / 169 (0.59%)	0 / 169 (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
Ear infection			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal abscess			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchitis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheitis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	1 / 169 (0.59%)
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 myocarditis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			

subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ketosis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight gain poor			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	½ (B+OMV) (Group V) Booster Phase	PH2 B+OMV (Group VI) Booster Phase	MenC (Group VII) Booster Phase
Total subjects affected by serious adverse events			
subjects affected / exposed	15 / 168 (8.93%)	9 / 165 (5.45%)	9 / 165 (5.45%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Fibroma			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Cleft palate repair			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			

subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site erythema			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Milk allergy			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenoidal hypertrophy			
subjects affected / exposed	1 / 168 (0.60%)	0 / 165 (0.00%)	1 / 165 (0.61%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 168 (0.00%)	1 / 165 (0.61%)	0 / 165 (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

Investigations			
Acoustic Stimulation Tests			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Bone fissure			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 168 (0.00%)	1 / 165 (0.61%)	0 / 165 (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
Foreign body aspiration			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed	1 / 168 (0.60%)	0 / 165 (0.00%)	0 / 165 (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
Head injury			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			

subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	1 / 165 (0.61%)
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	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental exposure to product			
subjects affected / exposed	1 / 168 (0.60%)	0 / 165 (0.00%)	0 / 165 (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, familial and genetic disorders			
Congenital megacolon			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cryptorchism			
subjects affected / exposed	1 / 168 (0.60%)	0 / 165 (0.00%)	0 / 165 (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
Phimosis			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Pulmonary valve stenosis			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 168 (0.00%)	1 / 165 (0.61%)	1 / 165 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotonia			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myoclonic epilepsy			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIth nerve paralysis			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			

subjects affected / exposed	1 / 168 (0.60%)	0 / 165 (0.00%)	0 / 165 (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
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 168 (0.00%)	1 / 165 (0.61%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis			
subjects affected / exposed	1 / 168 (0.60%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Aphthous stomatitis			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis haemorrhagic			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			

subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 168 (0.00%)	1 / 165 (0.61%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 168 (0.60%)	0 / 165 (0.00%)	0 / 165 (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	1 / 168 (0.60%)	0 / 165 (0.00%)	0 / 165 (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 and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriasis			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			

Acarodermatitis			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial pyelonephritis			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	1 / 168 (0.60%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	4 / 168 (2.38%)	1 / 165 (0.61%)	3 / 165 (1.82%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	1 / 168 (0.60%)	0 / 165 (0.00%)	0 / 165 (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
Corona virus infection			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			

subjects affected / exposed	1 / 168 (0.60%)	5 / 165 (3.03%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	1 / 168 (0.60%)	0 / 165 (0.00%)	0 / 165 (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 viral			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	2 / 168 (1.19%)	0 / 165 (0.00%)	2 / 165 (1.21%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	0 / 168 (0.00%)	1 / 165 (0.61%)	0 / 165 (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
Oral candidiasis			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral herpes			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			

subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis			

subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 168 (0.00%)	1 / 165 (0.61%)	0 / 165 (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 tonsillitis			

subjects affected / exposed	1 / 168 (0.60%)	0 / 165 (0.00%)	0 / 165 (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
Bullous impetigo			
subjects affected / exposed	1 / 168 (0.60%)	0 / 165 (0.00%)	0 / 165 (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
Cystitis			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear infection			
subjects affected / exposed	1 / 168 (0.60%)	0 / 165 (0.00%)	0 / 165 (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
Pharyngotonsillitis			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	1 / 165 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal abscess			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchitis			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	1 / 165 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheitis			

subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral myocarditis			
subjects affected / exposed	0 / 168 (0.00%)	1 / 165 (0.61%)	0 / 165 (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			
Decreased appetite			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	1 / 168 (0.60%)	0 / 165 (0.00%)	0 / 165 (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
Ketosis			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight gain poor			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Par+B+OMV (Group VIII) Booster Phase		
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 161 (8.70%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Fibroma			

subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neoplasm			
subjects affected / exposed	1 / 161 (0.62%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Cleft palate repair			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injection site erythema			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Milk allergy			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dyspnoea			

subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory distress			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adenoidal hypertrophy			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	1 / 161 (0.62%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Investigations			
Acoustic Stimulation Tests			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Bone fissure			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Concussion			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fall			

subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foreign body aspiration			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foreign body			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Head injury			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Joint dislocation			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Road traffic accident			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thermal burn			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Toxicity to various agents			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Accidental exposure to product			

subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Congenital megacolon			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cryptorchism			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Phimosis			
subjects affected / exposed	1 / 161 (0.62%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Pulmonary valve stenosis			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	3 / 161 (1.86%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Guillain-Barre syndrome			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypotonia			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Myoclonic epilepsy			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Partial seizures			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vlith nerve paralysis			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Somnolence			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Convulsion			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anaemia			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphadenitis			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			

Aphthous stomatitis				
subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enteritis				
subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterocolitis haemorrhagic				
subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastritis				
subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrooesophageal reflux disease				
subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inguinal hernia				
subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intussusception				

subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psoriasis			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rash			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Acarodermatitis			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bacterial pyelonephritis			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchiolitis			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchitis			
subjects affected / exposed	2 / 161 (1.24%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Bronchopneumonia			

subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Corona virus infection			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cytomegalovirus infection			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Exanthema subitum			
subjects affected / exposed	1 / 161 (0.62%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	3 / 161 (1.86%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis viral			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infection			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laryngitis			

subjects affected / exposed	1 / 161 (0.62%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nasopharyngitis				
subjects affected / exposed	1 / 161 (0.62%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Oral candidiasis				
subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oral herpes				
subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Otitis media acute				
subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pharyngitis				
subjects affected / exposed	1 / 161 (0.62%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia respiratory syncytial viral				
subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia viral				

subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis acute				
subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory syncytial virus infection				
subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rhinitis				
subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rhinovirus infection				
subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tonsillitis				

subjects affected / exposed	1 / 161 (0.62%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Varicella				
subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Viral infection				
subjects affected / exposed	2 / 161 (1.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Acute tonsillitis				
subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bullous impetigo				
subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cystitis				
subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device related sepsis				
subjects affected / exposed	0 / 161 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ear infection				

subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pharyngotonsillitis			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal abscess			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory syncytial virus bronchitis			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tracheitis			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral myocarditis			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dehydration			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ketosis			

subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Weight gain poor			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	B+OMV (Group I)	B+½ OMV (Group II)	B+1/4 OMV (Group III)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	181 / 184 (98.37%)	183 / 184 (99.46%)	186 / 189 (98.41%)
Nervous system disorders			
Somnolence			
subjects affected / exposed	145 / 184 (78.80%)	149 / 184 (80.98%)	146 / 189 (77.25%)
occurrences (all)	310	312	320
General disorders and administration site conditions			
Crying			
subjects affected / exposed	122 / 184 (66.30%)	135 / 184 (73.37%)	137 / 189 (72.49%)
occurrences (all)	284	301	276
Injection site erythema			
subjects affected / exposed	151 / 184 (82.07%)	150 / 184 (81.52%)	155 / 189 (82.01%)
occurrences (all)	865	853	887
Injection site induration			
subjects affected / exposed	141 / 184 (76.63%)	139 / 184 (75.54%)	141 / 189 (74.60%)
occurrences (all)	859	837	824
Injection site swelling			
subjects affected / exposed	97 / 184 (52.72%)	94 / 184 (51.09%)	103 / 189 (54.50%)
occurrences (all)	463	437	411
Injection site pain			
subjects affected / exposed	150 / 184 (81.52%)	157 / 184 (85.33%)	139 / 189 (73.54%)
occurrences (all)	927	896	780
Pyrexia			

subjects affected / exposed occurrences (all)	136 / 184 (73.91%) 270	127 / 184 (69.02%) 256	122 / 189 (64.55%) 209
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	84 / 184 (45.65%)	87 / 184 (47.28%)	80 / 189 (42.33%)
occurrences (all)	169	161	178
Vomiting			
subjects affected / exposed	38 / 184 (20.65%)	37 / 184 (20.11%)	42 / 189 (22.22%)
occurrences (all)	54	60	59
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	22 / 184 (11.96%)	21 / 184 (11.41%)	9 / 189 (4.76%)
occurrences (all)	32	27	11
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	10 / 184 (5.43%)	3 / 184 (1.63%)	7 / 189 (3.70%)
occurrences (all)	11	3	8
Rash			
subjects affected / exposed	15 / 184 (8.15%)	18 / 184 (9.78%)	15 / 189 (7.94%)
occurrences (all)	17	28	17
Psychiatric disorders			
Eating disorder			
subjects affected / exposed	105 / 184 (57.07%)	106 / 184 (57.61%)	104 / 189 (55.03%)
occurrences (all)	193	216	196
Irritability			
subjects affected / exposed	157 / 184 (85.33%)	159 / 184 (86.41%)	155 / 189 (82.01%)
occurrences (all)	402	381	385
Infections and infestations			
Bronchitis			
subjects affected / exposed	34 / 184 (18.48%)	34 / 184 (18.48%)	40 / 189 (21.16%)
occurrences (all)	45	54	56
Conjunctivitis			
subjects affected / exposed	14 / 184 (7.61%)	13 / 184 (7.07%)	14 / 189 (7.41%)
occurrences (all)	15	16	17
Ear infection			

subjects affected / exposed	10 / 184 (5.43%)	5 / 184 (2.72%)	10 / 189 (5.29%)
occurrences (all)	15	5	10
Exanthema subitum			
subjects affected / exposed	9 / 184 (4.89%)	18 / 184 (9.78%)	17 / 189 (8.99%)
occurrences (all)	9	18	17
Gastroenteritis			
subjects affected / exposed	10 / 184 (5.43%)	11 / 184 (5.98%)	6 / 189 (3.17%)
occurrences (all)	10	11	6
Nasopharyngitis			
subjects affected / exposed	20 / 184 (10.87%)	22 / 184 (11.96%)	25 / 189 (13.23%)
occurrences (all)	32	24	43
Pharyngitis			
subjects affected / exposed	21 / 184 (11.41%)	18 / 184 (9.78%)	15 / 189 (7.94%)
occurrences (all)	27	20	17
Rhinitis			
subjects affected / exposed	21 / 184 (11.41%)	14 / 184 (7.61%)	12 / 189 (6.35%)
occurrences (all)	23	18	13
Tonsillitis			
subjects affected / exposed	6 / 184 (3.26%)	3 / 184 (1.63%)	2 / 189 (1.06%)
occurrences (all)	6	3	2
Upper respiratory tract infection			
subjects affected / exposed	13 / 184 (7.07%)	13 / 184 (7.07%)	10 / 189 (5.29%)
occurrences (all)	15	15	10
Varicella			
subjects affected / exposed	5 / 184 (2.72%)	10 / 184 (5.43%)	2 / 189 (1.06%)
occurrences (all)	5	10	2
Viral infection			
subjects affected / exposed	19 / 184 (10.33%)	27 / 184 (14.67%)	23 / 189 (12.17%)
occurrences (all)	24	30	26

Non-serious adverse events	B (Group IV)	½ (B+OMV) (Group V)	PH2 B+OMV (Group VI)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	183 / 187 (97.86%)	180 / 187 (96.26%)	180 / 185 (97.30%)
Nervous system disorders			
Somnolence			

subjects affected / exposed occurrences (all)	131 / 187 (70.05%) 257	142 / 187 (75.94%) 298	143 / 185 (77.30%) 322
General disorders and administration site conditions			
Crying			
subjects affected / exposed	99 / 187 (52.94%)	125 / 187 (66.84%)	141 / 185 (76.22%)
occurrences (all)	208	273	341
Injection site erythema			
subjects affected / exposed	132 / 187 (70.59%)	131 / 187 (70.05%)	150 / 185 (81.08%)
occurrences (all)	661	707	811
Injection site induration			
subjects affected / exposed	126 / 187 (67.38%)	130 / 187 (69.52%)	130 / 185 (70.27%)
occurrences (all)	676	716	756
Injection site swelling			
subjects affected / exposed	80 / 187 (42.78%)	88 / 187 (47.06%)	100 / 185 (54.05%)
occurrences (all)	331	390	437
Injection site pain			
subjects affected / exposed	101 / 187 (54.01%)	131 / 187 (70.05%)	152 / 185 (82.16%)
occurrences (all)	487	761	960
Pyrexia			
subjects affected / exposed	71 / 187 (37.97%)	114 / 187 (60.96%)	126 / 185 (68.11%)
occurrences (all)	109	204	247
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	67 / 187 (35.83%)	80 / 187 (42.78%)	81 / 185 (43.78%)
occurrences (all)	132	143	161
Vomiting			
subjects affected / exposed	32 / 187 (17.11%)	36 / 187 (19.25%)	43 / 185 (23.24%)
occurrences (all)	51	58	67
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	19 / 187 (10.16%)	13 / 187 (6.95%)	19 / 185 (10.27%)
occurrences (all)	27	19	24
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 187 (0.00%)	6 / 187 (3.21%)	2 / 185 (1.08%)
occurrences (all)	0	6	2

Rash			
subjects affected / exposed	18 / 187 (9.63%)	24 / 187 (12.83%)	26 / 185 (14.05%)
occurrences (all)	21	32	32
Psychiatric disorders			
Eating disorder			
subjects affected / exposed	84 / 187 (44.92%)	112 / 187 (59.89%)	119 / 185 (64.32%)
occurrences (all)	154	200	242
Irritability			
subjects affected / exposed	139 / 187 (74.33%)	151 / 187 (80.75%)	153 / 185 (82.70%)
occurrences (all)	296	386	400
Infections and infestations			
Bronchitis			
subjects affected / exposed	31 / 187 (16.58%)	31 / 187 (16.58%)	43 / 185 (23.24%)
occurrences (all)	49	55	55
Conjunctivitis			
subjects affected / exposed	13 / 187 (6.95%)	15 / 187 (8.02%)	22 / 185 (11.89%)
occurrences (all)	17	19	28
Ear infection			
subjects affected / exposed	6 / 187 (3.21%)	7 / 187 (3.74%)	12 / 185 (6.49%)
occurrences (all)	7	10	18
Exanthema subitum			
subjects affected / exposed	17 / 187 (9.09%)	19 / 187 (10.16%)	13 / 185 (7.03%)
occurrences (all)	17	20	13
Gastroenteritis			
subjects affected / exposed	9 / 187 (4.81%)	6 / 187 (3.21%)	13 / 185 (7.03%)
occurrences (all)	9	7	16
Nasopharyngitis			
subjects affected / exposed	17 / 187 (9.09%)	19 / 187 (10.16%)	24 / 185 (12.97%)
occurrences (all)	22	27	31
Pharyngitis			
subjects affected / exposed	21 / 187 (11.23%)	25 / 187 (13.37%)	15 / 185 (8.11%)
occurrences (all)	28	30	21
Rhinitis			
subjects affected / exposed	19 / 187 (10.16%)	21 / 187 (11.23%)	26 / 185 (14.05%)
occurrences (all)	23	22	36
Tonsillitis			

subjects affected / exposed	12 / 187 (6.42%)	7 / 187 (3.74%)	5 / 185 (2.70%)
occurrences (all)	13	7	5
Upper respiratory tract infection			
subjects affected / exposed	10 / 187 (5.35%)	8 / 187 (4.28%)	12 / 185 (6.49%)
occurrences (all)	12	12	14
Varicella			
subjects affected / exposed	5 / 187 (2.67%)	7 / 187 (3.74%)	5 / 185 (2.70%)
occurrences (all)	5	7	5
Viral infection			
subjects affected / exposed	24 / 187 (12.83%)	24 / 187 (12.83%)	17 / 185 (9.19%)
occurrences (all)	31	33	21

Non-serious adverse events	MenC (Group VII)	183Par+B+OMV (Group VIII)	B+OMV (Group I) Booster Phase
Total subjects affected by non-serious adverse events			
subjects affected / exposed	175 / 184 (95.11%)	175 / 183 (95.63%)	151 / 155 (97.42%)
Nervous system disorders			
Somnolence			
subjects affected / exposed	113 / 184 (61.41%)	134 / 183 (73.22%)	76 / 155 (49.03%)
occurrences (all)	244	291	77
General disorders and administration site conditions			
Crying			
subjects affected / exposed	87 / 184 (47.28%)	112 / 183 (61.20%)	74 / 155 (47.74%)
occurrences (all)	167	211	79
Injection site erythema			
subjects affected / exposed	119 / 184 (64.67%)	132 / 183 (72.13%)	97 / 155 (62.58%)
occurrences (all)	594	661	246
Injection site induration			
subjects affected / exposed	122 / 184 (66.30%)	126 / 183 (68.85%)	81 / 155 (52.26%)
occurrences (all)	570	665	202
Injection site swelling			
subjects affected / exposed	75 / 184 (40.76%)	77 / 183 (42.08%)	57 / 155 (36.77%)
occurrences (all)	265	348	136
Injection site pain			
subjects affected / exposed	105 / 184 (57.07%)	119 / 183 (65.03%)	121 / 155 (78.06%)
occurrences (all)	490	595	326
Pyrexia			

subjects affected / exposed occurrences (all)	62 / 184 (33.70%) 97	78 / 183 (42.62%) 125	86 / 155 (55.48%) 94
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	74 / 184 (40.22%)	73 / 183 (39.89%)	31 / 155 (20.00%)
occurrences (all)	129	134	33
Vomiting			
subjects affected / exposed	34 / 184 (18.48%)	46 / 183 (25.14%)	6 / 155 (3.87%)
occurrences (all)	48	70	6
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	12 / 184 (6.52%)	10 / 183 (5.46%)	5 / 155 (3.23%)
occurrences (all)	15	12	6
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	13 / 184 (7.07%)	9 / 183 (4.92%)	0 / 155 (0.00%)
occurrences (all)	15	10	0
Rash			
subjects affected / exposed	16 / 184 (8.70%)	19 / 183 (10.38%)	8 / 155 (5.16%)
occurrences (all)	24	27	9
Psychiatric disorders			
Eating disorder			
subjects affected / exposed	63 / 184 (34.24%)	93 / 183 (50.82%)	74 / 155 (47.74%)
occurrences (all)	102	181	77
Irritability			
subjects affected / exposed	121 / 184 (65.76%)	137 / 183 (74.86%)	116 / 155 (74.84%)
occurrences (all)	258	311	123
Infections and infestations			
Bronchitis			
subjects affected / exposed	34 / 184 (18.48%)	35 / 183 (19.13%)	25 / 155 (16.13%)
occurrences (all)	46	52	28
Conjunctivitis			
subjects affected / exposed	10 / 184 (5.43%)	17 / 183 (9.29%)	7 / 155 (4.52%)
occurrences (all)	13	21	7
Ear infection			

subjects affected / exposed	9 / 184 (4.89%)	7 / 183 (3.83%)	8 / 155 (5.16%)
occurrences (all)	13	8	13
Exanthema subitum			
subjects affected / exposed	20 / 184 (10.87%)	11 / 183 (6.01%)	6 / 155 (3.87%)
occurrences (all)	20	12	6
Gastroenteritis			
subjects affected / exposed	7 / 184 (3.80%)	8 / 183 (4.37%)	5 / 155 (3.23%)
occurrences (all)	8	8	5
Nasopharyngitis			
subjects affected / exposed	16 / 184 (8.70%)	19 / 183 (10.38%)	15 / 155 (9.68%)
occurrences (all)	20	29	21
Pharyngitis			
subjects affected / exposed	18 / 184 (9.78%)	19 / 183 (10.38%)	11 / 155 (7.10%)
occurrences (all)	19	26	12
Rhinitis			
subjects affected / exposed	20 / 184 (10.87%)	12 / 183 (6.56%)	7 / 155 (4.52%)
occurrences (all)	22	18	7
Tonsillitis			
subjects affected / exposed	5 / 184 (2.72%)	4 / 183 (2.19%)	6 / 155 (3.87%)
occurrences (all)	5	4	7
Upper respiratory tract infection			
subjects affected / exposed	9 / 184 (4.89%)	9 / 183 (4.92%)	8 / 155 (5.16%)
occurrences (all)	11	9	9
Varicella			
subjects affected / exposed	5 / 184 (2.72%)	5 / 183 (2.73%)	0 / 155 (0.00%)
occurrences (all)	5	5	0
Viral infection			
subjects affected / exposed	16 / 184 (8.70%)	21 / 183 (11.48%)	12 / 155 (7.74%)
occurrences (all)	18	25	14

Non-serious adverse events	B+½ OMV (Group II) Booster Phase	B+1/4 OMV (Group III) Booster Phase	B (Group IV) Booster Phase
Total subjects affected by non-serious adverse events			
subjects affected / exposed	159 / 163 (97.55%)	162 / 169 (95.86%)	152 / 169 (89.94%)
Nervous system disorders			
Somnolence			

subjects affected / exposed occurrences (all)	90 / 163 (55.21%) 91	90 / 169 (53.25%) 97	63 / 169 (37.28%) 69
General disorders and administration site conditions			
Crying			
subjects affected / exposed	64 / 163 (39.26%)	69 / 169 (40.83%)	46 / 169 (27.22%)
occurrences (all)	69	76	50
Injection site erythema			
subjects affected / exposed	107 / 163 (65.64%)	120 / 169 (71.01%)	83 / 169 (49.11%)
occurrences (all)	281	321	204
Injection site induration			
subjects affected / exposed	90 / 163 (55.21%)	105 / 169 (62.13%)	71 / 169 (42.01%)
occurrences (all)	244	279	185
Injection site swelling			
subjects affected / exposed	63 / 163 (38.65%)	76 / 169 (44.97%)	46 / 169 (27.22%)
occurrences (all)	151	177	105
Injection site pain			
subjects affected / exposed	110 / 163 (67.48%)	126 / 169 (74.56%)	92 / 169 (54.44%)
occurrences (all)	310	339	242
Pyrexia			
subjects affected / exposed	94 / 163 (57.67%)	70 / 169 (41.42%)	49 / 169 (28.99%)
occurrences (all)	112	92	63
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	37 / 163 (22.70%)	39 / 169 (23.08%)	47 / 169 (27.81%)
occurrences (all)	41	45	58
Vomiting			
subjects affected / exposed	13 / 163 (7.98%)	7 / 169 (4.14%)	7 / 169 (4.14%)
occurrences (all)	14	7	9
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	12 / 163 (7.36%)	11 / 169 (6.51%)	9 / 169 (5.33%)
occurrences (all)	14	14	11
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 169 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0

Rash			
subjects affected / exposed	6 / 163 (3.68%)	11 / 169 (6.51%)	2 / 169 (1.18%)
occurrences (all)	7	11	2
Psychiatric disorders			
Eating disorder			
subjects affected / exposed	77 / 163 (47.24%)	79 / 169 (46.75%)	52 / 169 (30.77%)
occurrences (all)	79	89	61
Irritability			
subjects affected / exposed	111 / 163 (68.10%)	112 / 169 (66.27%)	86 / 169 (50.89%)
occurrences (all)	118	122	99
Infections and infestations			
Bronchitis			
subjects affected / exposed	18 / 163 (11.04%)	25 / 169 (14.79%)	28 / 169 (16.57%)
occurrences (all)	24	27	38
Conjunctivitis			
subjects affected / exposed	7 / 163 (4.29%)	5 / 169 (2.96%)	13 / 169 (7.69%)
occurrences (all)	7	5	14
Ear infection			
subjects affected / exposed	4 / 163 (2.45%)	2 / 169 (1.18%)	5 / 169 (2.96%)
occurrences (all)	6	2	7
Exanthema subitum			
subjects affected / exposed	7 / 163 (4.29%)	8 / 169 (4.73%)	5 / 169 (2.96%)
occurrences (all)	7	8	5
Gastroenteritis			
subjects affected / exposed	4 / 163 (2.45%)	8 / 169 (4.73%)	11 / 169 (6.51%)
occurrences (all)	4	9	11
Nasopharyngitis			
subjects affected / exposed	10 / 163 (6.13%)	18 / 169 (10.65%)	11 / 169 (6.51%)
occurrences (all)	12	20	11
Pharyngitis			
subjects affected / exposed	16 / 163 (9.82%)	13 / 169 (7.69%)	14 / 169 (8.28%)
occurrences (all)	17	15	16
Rhinitis			
subjects affected / exposed	9 / 163 (5.52%)	8 / 169 (4.73%)	11 / 169 (6.51%)
occurrences (all)	9	9	13
Tonsillitis			

subjects affected / exposed occurrences (all)	10 / 163 (6.13%) 11	4 / 169 (2.37%) 4	8 / 169 (4.73%) 8
Upper respiratory tract infection subjects affected / exposed occurrences (all)	7 / 163 (4.29%) 10	8 / 169 (4.73%) 11	9 / 169 (5.33%) 9
Varicella subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	0 / 169 (0.00%) 0	0 / 169 (0.00%) 0
Viral infection subjects affected / exposed occurrences (all)	14 / 163 (8.59%) 14	6 / 169 (3.55%) 10	16 / 169 (9.47%) 19

Non-serious adverse events	½ (B+OMV) (Group V) Booster Phase	PH2 B+OMV (Group VI) Booster Phase	MenC (Group VII) Booster Phase
Total subjects affected by non-serious adverse events subjects affected / exposed	154 / 168 (91.67%)	156 / 165 (94.55%)	155 / 165 (93.94%)
Nervous system disorders Somnolence subjects affected / exposed occurrences (all)	86 / 168 (51.19%) 92	88 / 165 (53.33%) 89	100 / 165 (60.61%) 149
General disorders and administration site conditions Crying subjects affected / exposed occurrences (all)	71 / 168 (42.26%) 79	82 / 165 (49.70%) 85	85 / 165 (51.52%) 114
Injection site erythema subjects affected / exposed occurrences (all)	89 / 168 (52.98%) 229	96 / 165 (58.18%) 241	110 / 165 (66.67%) 345
Injection site induration subjects affected / exposed occurrences (all)	76 / 168 (45.24%) 202	81 / 165 (49.09%) 204	97 / 165 (58.79%) 290
Injection site swelling subjects affected / exposed occurrences (all)	53 / 168 (31.55%) 124	57 / 165 (34.55%) 144	65 / 165 (39.39%) 157
Injection site pain subjects affected / exposed occurrences (all)	111 / 168 (66.07%) 309	116 / 165 (70.30%) 327	125 / 165 (75.76%) 398
Pyrexia			

subjects affected / exposed occurrences (all)	85 / 168 (50.60%) 102	72 / 165 (43.64%) 90	92 / 165 (55.76%) 137
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	34 / 168 (20.24%)	31 / 165 (18.79%)	40 / 165 (24.24%)
occurrences (all)	40	37	53
Vomiting			
subjects affected / exposed	10 / 168 (5.95%)	10 / 165 (6.06%)	15 / 165 (9.09%)
occurrences (all)	11	10	17
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	11 / 168 (6.55%)	8 / 165 (4.85%)	10 / 165 (6.06%)
occurrences (all)	15	9	11
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	9 / 168 (5.36%)	6 / 165 (3.64%)	12 / 165 (7.27%)
occurrences (all)	10	7	16
Psychiatric disorders			
Eating disorder			
subjects affected / exposed	70 / 168 (41.67%)	80 / 165 (48.48%)	72 / 165 (43.64%)
occurrences (all)	79	82	112
Irritability			
subjects affected / exposed	116 / 168 (69.05%)	115 / 165 (69.70%)	126 / 165 (76.36%)
occurrences (all)	126	123	203
Infections and infestations			
Bronchitis			
subjects affected / exposed	28 / 168 (16.67%)	19 / 165 (11.52%)	35 / 165 (21.21%)
occurrences (all)	39	26	54
Conjunctivitis			
subjects affected / exposed	8 / 168 (4.76%)	7 / 165 (4.24%)	6 / 165 (3.64%)
occurrences (all)	11	8	6
Ear infection			

subjects affected / exposed	9 / 168 (5.36%)	7 / 165 (4.24%)	11 / 165 (6.67%)
occurrences (all)	10	8	11
Exanthema subitum			
subjects affected / exposed	5 / 168 (2.98%)	6 / 165 (3.64%)	7 / 165 (4.24%)
occurrences (all)	5	6	7
Gastroenteritis			
subjects affected / exposed	12 / 168 (7.14%)	15 / 165 (9.09%)	9 / 165 (5.45%)
occurrences (all)	14	16	9
Nasopharyngitis			
subjects affected / exposed	14 / 168 (8.33%)	15 / 165 (9.09%)	14 / 165 (8.48%)
occurrences (all)	19	18	19
Pharyngitis			
subjects affected / exposed	22 / 168 (13.10%)	15 / 165 (9.09%)	16 / 165 (9.70%)
occurrences (all)	24	18	18
Rhinitis			
subjects affected / exposed	10 / 168 (5.95%)	8 / 165 (4.85%)	6 / 165 (3.64%)
occurrences (all)	13	8	7
Tonsillitis			
subjects affected / exposed	5 / 168 (2.98%)	8 / 165 (4.85%)	6 / 165 (3.64%)
occurrences (all)	5	8	6
Upper respiratory tract infection			
subjects affected / exposed	7 / 168 (4.17%)	9 / 165 (5.45%)	8 / 165 (4.85%)
occurrences (all)	8	10	12
Varicella			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	0 / 165 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	18 / 168 (10.71%)	9 / 165 (5.45%)	12 / 165 (7.27%)
occurrences (all)	20	11	15

Non-serious adverse events	Par+B+OMV (Group VIII) Booster Phase		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	150 / 161 (93.17%)		
Nervous system disorders			
Somnolence			

subjects affected / exposed	80 / 161 (49.69%)		
occurrences (all)	83		
General disorders and administration site conditions			
Crying			
subjects affected / exposed	50 / 161 (31.06%)		
occurrences (all)	52		
Injection site erythema			
subjects affected / exposed	88 / 161 (54.66%)		
occurrences (all)	234		
Injection site induration			
subjects affected / exposed	70 / 161 (43.48%)		
occurrences (all)	186		
Injection site swelling			
subjects affected / exposed	50 / 161 (31.06%)		
occurrences (all)	119		
Injection site pain			
subjects affected / exposed	97 / 161 (60.25%)		
occurrences (all)	255		
Pyrexia			
subjects affected / exposed	59 / 161 (36.65%)		
occurrences (all)	68		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	34 / 161 (21.12%)		
occurrences (all)	34		
Vomiting			
subjects affected / exposed	20 / 161 (12.42%)		
occurrences (all)	21		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	7 / 161 (4.35%)		
occurrences (all)	9		
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences (all)	0		

Rash subjects affected / exposed occurrences (all)	7 / 161 (4.35%) 8		
Psychiatric disorders Eating disorder subjects affected / exposed occurrences (all)	66 / 161 (40.99%) 67		
Irritability subjects affected / exposed occurrences (all)	96 / 161 (59.63%) 102		
Infections and infestations Bronchitis subjects affected / exposed occurrences (all)	17 / 161 (10.56%) 19		
Conjunctivitis subjects affected / exposed occurrences (all)	10 / 161 (6.21%) 10		
Ear infection subjects affected / exposed occurrences (all)	4 / 161 (2.48%) 5		
Exanthema subitum subjects affected / exposed occurrences (all)	10 / 161 (6.21%) 10		
Gastroenteritis subjects affected / exposed occurrences (all)	7 / 161 (4.35%) 7		
Nasopharyngitis subjects affected / exposed occurrences (all)	7 / 161 (4.35%) 10		
Pharyngitis subjects affected / exposed occurrences (all)	15 / 161 (9.32%) 18		
Rhinitis subjects affected / exposed occurrences (all)	6 / 161 (3.73%) 8		
Tonsillitis			

subjects affected / exposed	9 / 161 (5.59%)		
occurrences (all)	9		
Upper respiratory tract infection			
subjects affected / exposed	5 / 161 (3.11%)		
occurrences (all)	5		
Varicella			
subjects affected / exposed	0 / 161 (0.00%)		
occurrences (all)	0		
Viral infection			
subjects affected / exposed	11 / 161 (6.83%)		
occurrences (all)	13		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 January 2010	To allow subjects participating in V72P16 to participate in a Booster Phase of the study in order to receive a fourth (booster) dose of the same formulation of MenB vaccine received during primary immunization concomitantly with a booster (fourth) dose of test routine vaccines, InfanrixHexa and Prevenar. To offer a dose of Menjugate as non-test vaccine to all subjects who participated in the study in Countries where serogroup C meningococcal conjugate vaccination is recommended, with the aim of ensuring the expected level of medical care. Menjugate will be administered either during the Booster Phase of the current trial or in an ad hoc visit for those subjects not participating in the Booster Phase.
09 December 2010	To include the serological testing of concomitant antigens in Study Group III (and Group VII as a control) in order to explore the effect of MenB vaccinations on the antibody response to concomitant vaccines. To clarify which interim analyses are performed.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

N/A

Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/24763084>

<http://www.ncbi.nlm.nih.gov/pubmed/25153133>