



Clinical trial results:

A phase IIIb randomised, open, controlled study to assess the safety, reactogenicity and immunogenicity of GlaxoSmithKline (GSK) Biologicals' 10-valent pneumococcal conjugate vaccine when co-administered with DTPa-combined, MenC and Hib-MenC vaccines in children as a 3-dose primary immunization course during the first 6 months of age.

Summary

| | |
|--------------------------|-----------------|
| EudraCT number | 2006-000558-30 |
| Trial protocol | DE ES |
| Global end of trial date | 24 October 2007 |

Results information

| | |
|--------------------------------|---------------|
| Result version number | v1 (current) |
| This version publication date | 07 March 2016 |
| First version publication date | 12 June 2015 |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | 107005 |
|-----------------------|--------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT00334334 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

| | |
|--|------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 27 November 2013 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 23 April 2007 |
| Global end of trial reached? | Yes |
| Global end of trial date | 24 October 2007 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The main objective of the study is to demonstrate that GSK Biologicals' 10-valent pneumococcal conjugate vaccine, when administered as a 3-dose primary vaccination course, is non-inferior to Prevenar, both co-administered with DTPa-HBV-IPV and Hib-MenC vaccines, in terms of post-immunization febrile reactions with rectal fever > 39.0°C. Criteria for safety: Non-inferiority will be demonstrated if the upper limit of the 95% CI of the difference (10Pn-PD-DiT + Hib-MenC Group minus Prevenar Group), in terms of percentage of subjects with rectal fever >39.0°C, is lower than 10%.

Protection of trial subjects:

Vaccines were administered by qualified and trained personnel and only to eligible subjects that had no contraindications to any components of the vaccines. In addition, specific adverse events (AEs) constituted absolute contraindications to further vaccination; if occurring, the subject did not receive additional doses of vaccine, continued other study procedures at the discretion of the investigator and was followed until resolution of the AE. AEs motivating ending of vaccination were any anaphylactic reaction post vaccination, acute disease at time of vaccination (= presence of moderate or severe illness with/without fever; vaccines were given in case of minor illnesses like diarrhea or mild upper respiratory infection with/without low-grade fever [i.e. Oral/Axillary/Tympanic temperature (T) < 37.5°C/Rectal T < 38.0°C] with visit postponed until improvement) and febrile illness (= oral, axillary or tympanic T ≥ 37.5°C, rectal T ≥ 38.0°C - T ≥ these cut-offs warranted deferral of vaccination pending recovery). Also, for the DTPa-HBV-IPV/Hib or DTPa-HBV-IPV vaccine, experience of encephalopathy (= acute, severe central nervous system disorder within 7 days post vaccination lasting more than a few hours, with failure to recover within 24 hours) constituted absolute contraindications to vaccination. For these vaccines, specific precautions were taken in case of rectal T ≥ 40.5°C or oral, axillary or tympanic T ≥ 40.0°C within 48 hours of vaccination, collapse or shock-like state (hypotonic-hyporesponsive episode) within 48 hours of vaccination, persistent, inconsolable crying within 48 hours of vaccination and lasting ≥ 3 hours and seizures with/without fever occurring within 3 days of vaccination. For Prevenar, moderate to severe illness, with/without fever was a reason to defer immunization. For NeisVac-C and Meningitec, vaccines were given with caution to individuals with thrombocytopenia or any coagulation disorder.

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 12 June 2006 |
| 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? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|--------------|
| Country: Number of subjects enrolled | Spain: 519 |
| Country: Number of subjects enrolled | Germany: 413 |

| | |
|--------------------------------------|-------------|
| Country: Number of subjects enrolled | Poland: 640 |
| Worldwide total number of subjects | 1572 |
| EEA total number of subjects | 1572 |

Notes:

| Subjects enrolled per age group | |
|---|------|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 1572 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

The study included an Active Phase, till about 7 months of age, and an Extended Safety Follow-Up (ESFU) Phase, till about 12 months of age.

Pre-assignment

Screening details:

1572 subjects were enrolled in the study and vaccinated out of which 24 subjects from a center located in Germany (6 in each group) were later eliminated and excluded from efficacy analyses due to protocol compliance following findings of a for cause audit; Safety results for these subjects are reported in this summary.

Period 1

| | |
|------------------------------|--------------------------------|
| Period 1 title | Overall Trial (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|----------------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | GSK 1024850A + Meningitec™ Group |

Arm description:

Subjects were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (also referred to as 10Pn-PD-DiT or 10Pn vaccine) co-administered with Infanrix™ hexa (also referred to as DTPa-HBV-IPV/Hib). In addition, subjects also received Wyeth's Men-C conjugate vaccine (Meningitec™, also referred to as Men vaccine) at 2 and 4 months of age. For subjects in Poland and to comply with national recommendations, subjects were also offered a third dose of Meningitec™ at approximately 7 months of age, after the blood sampling performed at that time point. All vaccines were administered intramuscularly (IM), 10Pn in the right thigh, Infanrix™ hexa in the upper left thigh and Meningitec™ in the lower left thigh.

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | 10-valent Streptococcus pneumoniae conjugate vaccine |
| Investigational medicinal product code | |
| Other name | 10Pn, 10Pn-PD-DiT, Synflorix™, GlaxoSmithKline (GSK) Biologicals' 1024850A vaccine, GSK1024850A |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Three doses of the vaccine were administered intramuscularly, in the lower left thigh at 2, 4 and 6 months of age.

| | |
|--|---|
| Investigational medicinal product name | Infanrix™ Hexa |
| Investigational medicinal product code | |
| Other name | DTPa-IPV-HBV/Hib, Infanrix Hexa |
| Pharmaceutical forms | Powder and solvent for suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Two doses were administered intramuscularly in the lower left thigh at 2 and 4 months of age. Subjects in Poland, to comply with national recommendations, were also offered a third dose at approximately 7 months of age, after blood sampling.

| | |
|--|---|
| Investigational medicinal product name | Meningitec™ |
| Investigational medicinal product code | |
| Other name | Wyeth's conjugated meningococcal C vaccine, Meningitec™ |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

One dose of the vaccine was administered, in the lower left thigh or deltoid.

| | |
|------------------|---------------------------------|
| Arm title | GSK 1024850A + NeisVac-C™ Group |
|------------------|---------------------------------|

Arm description:

Subjects were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (also referred to as 10Pn-PD-DiT or 10Pn vaccine) co-administered with Infanrix™ hexa (also referred to as DTPa-HBV-IPV/Hib). In addition, subjects also received Baxter's Men-C conjugate vaccine (NeisVac-C™, also referred to as Neis vaccine) at 2 and 4 months of age. For subjects in Poland and to comply with national recommendations, subjects were also offered a third dose of NeisVac-C™, at approximately 7 months of age, after the blood sampling performed at that time point. All vaccines were administered intramuscularly (IM), 10Pn in the right thigh, Infanrix™ hexa in the upper left thigh and NeisVac-C™, in the lower left thigh.

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | 10-valent Streptococcus pneumoniae conjugate vaccine |
| Investigational medicinal product code | |
| Other name | 10Pn, 10Pn-PD-DiT, Synflorix™, GlaxoSmithKline (GSK) Biologicals' 1024850A vaccine, GSK1024850A |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Three doses of the vaccine were administered intramuscularly, in the lower left thigh at 2, 4 and 6 months of age.

| | |
|--|---|
| Investigational medicinal product name | Infanrix™ Hexa |
| Investigational medicinal product code | |
| Other name | DTPa-IPV-HBV/Hib, Infanrix Hexa |
| Pharmaceutical forms | Powder and solvent for suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Two doses were administered intramuscularly in the lower left thigh at 2 and 4 months of age. Subjects in Poland, to comply with national recommendations, were also offered a third dose at approximately 7 months of age, after blood sampling.

| | |
|--|--|
| Investigational medicinal product name | NeisVac-C |
| Investigational medicinal product code | |
| Other name | Baxter's meningococcal C conjugate vaccine, NeisVac-C™ |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

One dose of the vaccine was administered, in the lower left thigh or deltoid.

| | |
|------------------|---------------------------------|
| Arm title | GSK 1024850A + Menitorix™ Group |
|------------------|---------------------------------|

Arm description:

The Group is also referred to as the 10Pn-PD-DiT + Hib-MenC Group and included subjects who were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (also referred to as 10Pn-PD-DiT or 10Pn vaccine) co-administered with Infanrix™ pent (also referred to as DTPa-HBV-IPV) and with Menitorix™ (HibMenC). All vaccines were administered intramuscularly (IM), 10Pn in the right thigh, Infanrix™ penta in the upper left thigh and Menitorix™ in the lower left thigh.

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | 10-valent Streptococcus pneumoniae conjugate vaccine |
| Investigational medicinal product code | |
| Other name | 10Pn, 10Pn-PD-DiT, Synflorix™, GlaxoSmithKline (GSK) Biologicals' 1024850A vaccine, GSK1024850A |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Three doses of the vaccine were administered intramuscularly, in the lower left thigh at 2, 4 and 6 months of age.

| | |
|--|-------------------------------|
| Investigational medicinal product name | Infanrix penta |
| Investigational medicinal product code | |
| Other name | DTPa-HBV-IPV, Infanrix™ penta |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Two doses were administered intramuscularly in the lower left thigh at 2 and 4 months of age. Subjects in Poland, to comply with national recommendations, were also offered a third dose at approximately 7 months of age, after blood sampling.

| | |
|--|---|
| Investigational medicinal product name | Menitorix |
| Investigational medicinal product code | |
| Other name | GSK Biologicals' combined Haemophilus influenzae type b - meningococcal serogroup vaccine, Hib-MenC, Menitorix™ |
| Pharmaceutical forms | Powder and solvent for solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Three doses of the vaccine were administered, in the lower left thigh at 2,4 and 6 months of age.

| | |
|------------------|------------------------------|
| Arm title | Prevenar™ + Menitorix™ Group |
|------------------|------------------------------|

Arm description:

The Group is also referred to as the Prevenar Group and included Subjects were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of Wyeth's 7-valent pneumococcal conjugate vaccine (Prevenar™ or 7Pn) co-administered with Infanrix™ penta and Menitorix™, GSK Biologicals' combined Hib-MenC vaccine (also referred to as HibMenC). All vaccines were administered intramuscularly (IM), Prevenar™ in the right thigh, Infanrix™ penta in the upper left thigh and Menitorix™, in the lower left thigh.

| | |
|--|---|
| Arm type | Active comparator |
| Investigational medicinal product name | Prevenar |
| Investigational medicinal product code | |
| Other name | Wyeth Lederle's 7-valent pneumococcal conjugate vaccine, 7Pn, Prevenar™ |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Three doses of the vaccine were administered intramuscularly, in the lower left thigh at 2, 4 and 6 months of age.

| | |
|--|-------------------------------|
| Investigational medicinal product name | Infanrix penta |
| Investigational medicinal product code | |
| Other name | DTPa-HBV-IPV, Infanrix™ penta |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Two doses were administered intramuscularly in the lower left thigh at 2 and 4 months of age. Subjects in Poland, to comply with national recommendations, were also offered a third dose at approximately 7 months of age, after blood sampling.

| | |
|--|---|
| Investigational medicinal product name | Menitorix |
| Investigational medicinal product code | |
| Other name | GSK Biologicals' combined Haemophilus influenzae type b - meningococcal serogroup vaccine, Hib-MenC, Menitorix™ |
| Pharmaceutical forms | Powder and solvent for solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Three doses of the vaccine were administered, in the lower left thigh at 2,4 and 6 months of age.

| Number of subjects in period 1 | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group |
|---------------------------------------|---|--|--|
| Started | 391 | 393 | 392 |
| Completed | 376 | 374 | 373 |
| Not completed | 15 | 19 | 19 |
| Adverse event, serious fatal | - | 1 | 1 |
| Consent withdrawn by subject | 1 | 1 | - |
| Adverse event, non-fatal | 1 | - | - |
| Other: protocol compliance issues | 6 | 6 | 6 |
| Migrated/moved from study area | - | - | - |
| Lost to follow-up | 3 | 6 | 2 |
| Protocol deviation | 4 | 5 | 10 |

| Number of subjects in period 1 | Prevenar™ + Menitorix™ Group |
|---------------------------------------|-------------------------------------|
| Started | 396 |
| Completed | 376 |
| Not completed | 20 |
| Adverse event, serious fatal | - |
| Consent withdrawn by subject | 1 |
| Adverse event, non-fatal | - |
| Other: protocol compliance issues | 6 |
| Migrated/moved from study area | 1 |
| Lost to follow-up | 3 |
| Protocol deviation | 9 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|----------------------------------|
| Reporting group title | GSK 1024850A + Meningitec™ Group |
|-----------------------|----------------------------------|

Reporting group description:

Subjects were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (also referred to as 10Pn-PD-DiT or 10Pn vaccine) co-administered with Infanrix™ hexa (also referred to as DTPa-HBV-IPV/Hib). In addition, subjects also received Wyeth's Men-C conjugate vaccine (Meningitec™, also referred to as Men vaccine) at 2 and 4 months of age. For subjects in Poland and to comply with national recommendations, subjects were also offered a third dose of Meningitec™ at approximately 7 months of age, after the blood sampling performed at that time point. All vaccines were administered intramuscularly (IM), 10Pn in the right thigh, Infanrix™ hexa in the upper left thigh and Meningitec™ in the lower left thigh.

| | |
|-----------------------|---------------------------------|
| Reporting group title | GSK 1024850A + NeisVac-C™ Group |
|-----------------------|---------------------------------|

Reporting group description:

Subjects were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (also referred to as 10Pn-PD-DiT or 10Pn vaccine) co-administered with Infanrix™ hexa (also referred to as DTPa-HBV-IPV/Hib). In addition, subjects also received Baxter's Men-C conjugate vaccine (NeisVac-C™, also referred to as Neis vaccine) at 2 and 4 months of age. For subjects in Poland and to comply with national recommendations, subjects were also offered a third dose of NeisVac-C™, at approximately 7 months of age, after the blood sampling performed at that time point. All vaccines were administered intramuscularly (IM), 10Pn in the right thigh, Infanrix™ hexa in the upper left thigh and NeisVac-C™, in the lower left thigh.

| | |
|-----------------------|---------------------------------|
| Reporting group title | GSK 1024850A + Menitorix™ Group |
|-----------------------|---------------------------------|

Reporting group description:

The Group is also referred to as the 10Pn-PD-DiT + Hib-MenC Group and included subjects who were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (also referred to as 10Pn-PD-DiT or 10Pn vaccine) co-administered with Infanrix™ pent (also referred to as DTPa-HBV-IPV) and with Menitorix™ (HibMenC). All vaccines were administered intramuscularly (IM), 10Pn in the right thigh, Infanrix™ penta in the upper left thigh and Menitorix™ in the lower left thigh.

| | |
|-----------------------|------------------------------|
| Reporting group title | Prevenar™ + Menitorix™ Group |
|-----------------------|------------------------------|

Reporting group description:

The Group is also referred to as the Prevenar Group and included Subjects were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of Wyeth's 7-valent pneumococcal conjugate vaccine (Prevenar™ or 7Pn) co-administered with Infanrix™ penta and Menitorix™, GSK Biologicals' combined Hib-MenC vaccine (also referred to as HibMenC). All vaccines were administered intramuscularly (IM), Prevenar™ in the right thigh, Infanrix™ penta in the upper left thigh and Menitorix™, in the lower left thigh.

| Reporting group values | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group |
|--|----------------------------------|---------------------------------|---------------------------------|
| Number of subjects | 391 | 393 | 392 |
| 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: weeks arithmetic mean standard deviation | 8.3 ± 2.36 | 8.4 ± 2.31 | 8.4 ± 2.36 |
| Gender categorical Units: Subjects | | | |
| Female | 192 | 187 | 216 |
| Male | 199 | 206 | 176 |

| Reporting group values | Prevenar™ + Menitorix™ Group | Total | |
|---|---------------------------------|-------|--|
| Number of subjects | 396 | 1572 | |
| 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 | |
| Age continuous Units: weeks arithmetic mean standard deviation | 8.4 ± 2.38 | - | |
| Gender categorical Units: Subjects | | | |
| Female | 187 | 782 | |
| Male | 209 | 790 | |

End points

End points reporting groups

| | |
|---|----------------------------------|
| Reporting group title | GSK 1024850A + Meningitec™ Group |
| Reporting group description: Subjects were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (also referred to as 10Pn-PD-DiT or 10Pn vaccine) co-administered with Infanrix™ hexa (also referred to as DTPa-HBV-IPV/Hib). In addition, subjects also received Wyeth's Men-C conjugate vaccine (Meningitec™, also referred to as Men vaccine) at 2 and 4 months of age. For subjects in Poland and to comply with national recommendations, subjects were also offered a third dose of Meningitec™ at approximately 7 months of age, after the blood sampling performed at that time point. All vaccines were administered intramuscularly (IM), 10Pn in the right thigh, Infanrix™ hexa in the upper left thigh and Meningitec™ in the lower left thigh. | |
| Reporting group title | GSK 1024850A + NeisVac-C™ Group |
| Reporting group description: Subjects were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (also referred to as 10Pn-PD-DiT or 10Pn vaccine) co-administered with Infanrix™ hexa (also referred to as DTPa-HBV-IPV/Hib). In addition, subjects also received Baxter's Men-C conjugate vaccine (NeisVac-C™, also referred to as Neis vaccine) at 2 and 4 months of age. For subjects in Poland and to comply with national recommendations, subjects were also offered a third dose of NeisVac-C™, at approximately 7 months of age, after the blood sampling performed at that time point. All vaccines were administered intramuscularly (IM), 10Pn in the right thigh, Infanrix™ hexa in the upper left thigh and NeisVac-C™, in the lower left thigh. | |
| Reporting group title | GSK 1024850A + Menitorix™ Group |
| Reporting group description: The Group is also referred to as the 10Pn-PD-DiT + Hib-MenC Group and included subjects who were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (also referred to as 10Pn-PD-DiT or 10Pn vaccine) co-administered with Infanrix™ pent (also referred to as DTPa-HBV-IPV) and with Menitorix™ (HibMenC). All vaccines were administered intramuscularly (IM), 10Pn in the right thigh, Infanrix™ penta in the upper left thigh and Menitorix™ in the lower left thigh. | |
| Reporting group title | Prevenar™ + Menitorix™ Group |
| Reporting group description: The Group is also referred to as the Prevenar Group and included Subjects were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of Wyeth's 7-valent pneumococcal conjugate vaccine (Prevenar™ or 7Pn) co-administered with Infanrix™ penta and Menitorix™, GSK Biologicals' combined Hib-MenC vaccine (also referred to as HibMenC). All vaccines were administered intramuscularly (IM), Prevenar™ in the right thigh, Infanrix™ penta in the upper left thigh and Menitorix™, in the lower left thigh. | |

Primary: Number of subjects reporting fever above (>) 39.0 degree Celsius (°C)

| | |
|---|--|
| End point title | Number of subjects reporting fever above (>) 39.0 degree Celsius (°C) ^[1] |
| End point description: Fever was measured as rectal temperature. Assessment of occurrences of fever > 39.0 °C was performed post doses 1, 2 and 3 of 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines). This endpoint concerns subjects with at least one vaccination dose documented at the exclusion of the 24 subjects from a center located in Germany (6 in each group) were later eliminated and excluded from efficacy analyses due to protocol compliance following findings of a for cause audit. | |
| End point type | Primary |
| End point timeframe: Within 4 days (Day 0-3) after each vaccination and across all doses | |

Notes:

[1] - 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: Inferential analysis was only applicable and applied to the GSK 1024850A + Menitorix™

| End point values | GSK 1024850A + Menitorix™ Group | Prevenar™ + Menitorix™ Group | | |
|-----------------------------|--|-------------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 381 | 386 | | |
| Units: Subjects | | | | |
| Post Dose 1 (N=381;386) | 9 | 4 | | |
| Post Dose 2 (N=379;385) | 11 | 11 | | |
| Post Dose 3 (N=370;375) | 9 | 11 | | |
| Across doses (N=381;386) | 23 | 24 | | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Non-inferiority of 10Pn vs 7Pn – Post Dose 1 |
| Comparison groups | GSK 1024850A + Menitorix™ Group v Prevenar™ + Menitorix™ Group |
| Number of subjects included in analysis | 767 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[2] |
| Parameter estimate | Difference in percentage |
| Point estimate | 1.33 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.57 |
| upper limit | 3.51 |

Notes:

[2] - Analysis assessed the difference in percentage of subjects reporting fever >39.0°C. Non-inferiority was demonstrated if the upper limit of the standardized asymptotic 95% confidence interval of the difference (GSK 1024850A + Menitorix™ Group minus Prevenar™ + Menitorix™ Group), in terms of percentage of subjects with rectal fever >39.0°C, was lower than 10%.

| | |
|---|--|
| Statistical analysis title | Non-inferiority of 10Pn vs 7Pn – Post Dose 2 |
| Comparison groups | GSK 1024850A + Menitorix™ Group v Prevenar™ + Menitorix™ Group |
| Number of subjects included in analysis | 767 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[3] |
| Parameter estimate | Difference in percentage |
| Point estimate | 0.05 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.45 |
| upper limit | 2.6 |

Notes:

[3] - Analysis assessed the difference in percentage of subjects reporting fever >39.0°C. Non-inferiority was demonstrated if the upper limit of the standardized asymptotic 95% confidence interval of the difference (GSK 1024850A + Menitorix™ Group minus Prevenar™ + Menitorix™ Group), in terms of

percentage of subjects with rectal fever >39.0°C, was lower than 10%.

| | |
|---|--|
| Statistical analysis title | Non-inferiority of 10Pn vs 7Pn – Post Dose 3 |
| Comparison groups | GSK 1024850A + Menitorix™ Group v Prevenar™ + Menitorix™ Group |
| Number of subjects included in analysis | 767 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[4] |
| Parameter estimate | Difference in percentage |
| Point estimate | -0.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -3.04 |
| upper limit | 1.98 |

Notes:

[4] - Analysis assessed the difference in percentage of subjects reporting fever >39.0°C. Non-inferiority was demonstrated if the upper limit of the standardized asymptotic 95% confidence interval of the difference (GSK 1024850A + Menitorix™ Group minus Prevenar™ + Menitorix™ Group), in terms of percentage of subjects with rectal fever >39.0°C, was lower than 10%.

| | |
|---|--|
| Statistical analysis title | Non-inferiority of 10Pn vs 7Pn – Across doses |
| Comparison groups | GSK 1024850A + Menitorix™ Group v Prevenar™ + Menitorix™ Group |
| Number of subjects included in analysis | 767 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[5] |
| Parameter estimate | Difference in percentage |
| Point estimate | -0.18 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -3.68 |
| upper limit | 3.32 |

Notes:

[5] - Analysis assessed the difference in percentage of subjects reporting fever >39.0°C. Non-inferiority was demonstrated if the upper limit of the standardized asymptotic 95% confidence interval of the difference (GSK 1024850A + Menitorix™ Group minus Prevenar™ + Menitorix™ Group), in terms of percentage of subjects with rectal fever >39.0°C, was lower than 10%.

Secondary: Number of subjects with any and any Grade 3 solicited local symptoms

| | |
|-----------------|--|
| End point title | Number of subjects with any and any Grade 3 solicited local symptoms |
|-----------------|--|

End point description:

Solicited local symptoms assessed include pain, redness and swelling. Grade 3 (G3) pain was defined as crying when limb was moved/spontaneously painful. G3 swelling/redness was defined as swelling/redness larger than (>) 30 millimeters (mm). "Any" is defined as incidence of the specified symptom regardless of intensity. This endpoint concerns subjects with at least one vaccination dose documented and with results available. The 24 subjects from a center located in Germany (6 in each group) who were later eliminated and excluded from efficacy analyses due to protocol compliance following findings of a for cause audit were not taken into account in this analysis.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Within 4 days (Day 0-3) after each vaccination and across all doses

| End point values | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group | Prevenar™ + Menitorix™ Group |
|---|---|--|--|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 381 | 380 | 381 | 386 |
| Units: Subjects | | | | |
| Any Pain, Post Dose 1 (N=380;380;381;386) | 157 | 157 | 146 | 120 |
| G3 Pain, Post Dose 1 (N=380;380;381;386) | 20 | 15 | 18 | 11 |
| Any Redness, Post Dose 1 (N=380;380;381;386) | 172 | 172 | 171 | 155 |
| G3 Redness, Post Dose 1 (N=380;380;381;386) | 9 | 4 | 4 | 3 |
| Any Swelling, Post Dose 1 (N=380;380;381;386) | 143 | 120 | 133 | 108 |
| G3 Swelling, Post Dose 1 (N=380;380;381;386) | 16 | 7 | 5 | 4 |
| Any Pain, Post Dose 2 (N=377;376;379;385) | 131 | 119 | 128 | 121 |
| G3 Pain, Post Dose 2 (N=377;376;379;385) | 11 | 13 | 11 | 9 |
| Any Redness, Post Dose 2 (N=377;376;379;385) | 180 | 164 | 178 | 164 |
| G3 Redness, Post Dose 2 (N=377;376;379;385) | 8 | 7 | 5 | 5 |
| Any Swelling, Post Dose 2 (N=377;376;379;385) | 143 | 122 | 132 | 113 |
| G3 Swelling, Post Dose 2 (N=377;376;379;385) | 11 | 9 | 5 | 6 |
| Any Pain, Post Dose 3 (N=373;373;370;375) | 100 | 110 | 123 | 100 |
| G3 Pain, Post Dose 3 (N=373;373;370;375) | 4 | 2 | 5 | 3 |
| Any Redness, Post Dose 3 (N=373;373;370;375) | 177 | 164 | 169 | 172 |
| G3 Redness, Post Dose 3 (N=373;373;370;375) | 11 | 6 | 3 | 8 |
| Any Swelling, Post Dose 3 (N=373;373;370;375) | 137 | 124 | 143 | 137 |
| G3 Swelling, Post Dose 3 (N=373;373;370;375) | 8 | 6 | 4 | 9 |
| Any Pain, Across Doses (N=381;380;381;386) | 213 | 208 | 212 | 185 |
| G3 Pain, Across Doses (N=381;380;381;386) | 28 | 26 | 28 | 20 |
| Any Redness, Across Doses (N=381;380;381;386) | 255 | 236 | 242 | 239 |
| G3 Redness, Across Doses (N=381;380;381;386) | 21 | 16 | 9 | 12 |
| Any Swelling, Across Doses (N=381;380;381;386) | 216 | 189 | 207 | 190 |
| G3 Swelling, Across Doses (N=381;380;381;386) | 28 | 20 | 12 | 17 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any and any Grade 3 solicited general symptoms

| | |
|-----------------|--|
| End point title | Number of subjects with any and any Grade 3 solicited general symptoms |
|-----------------|--|

End point description:

Solicited general symptoms assessed include drowsiness (Drows), fever, irritability (Irr), and loss of appetite (Loss App). Grade 3 (G3) Drows was defined as drowsiness which prevented normal everyday activities. G3 fever was defined as fever (rectal temperature) above (>) 39.0 degree Celsius (°C). G3 Irr was defined as crying that could not be comforted/preventing normal everyday activities. G3 Loss App was defined as the subject not eating at all. "Any" is defined as incidence of the specified symptom regardless of intensity or relationship to study vaccination. This endpoint concerns subjects with at least one vaccination dose documented and with results available. The 24 subjects from a center located in Germany (6 in each group) who were later eliminated and excluded from efficacy analyses due to protocol compliance following findings of a for cause audit were not taken into account in this analysis.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Within 4 days (Day 0-3) after each vaccination dose (D) and across all doses (AD)

| End point values | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group | Prevenar™ + Menitorix™ Group |
|---|----------------------------------|---------------------------------|---------------------------------|------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 381 | 380 | 381 | 386 |
| Units: Subjects | | | | |
| Any Drows, Post D1 (N=381;380;381;386) | 211 | 218 | 199 | 156 |
| G3 Drows, Post D1 (N=381;380;381;386) | 8 | 9 | 7 | 5 |
| Any Fever, Post D1 (N=381;380;381;386) | 166 | 192 | 141 | 95 |
| G3 Fever, Post D1 (N=381;380;381;386) | 12 | 15 | 9 | 4 |
| Any Irr , Post D1 (N=381;380;381;386) | 230 | 241 | 223 | 194 |
| G3 Irr, Post D1 (N=381;380;381;386) | 27 | 16 | 18 | 15 |
| Any Loss App, Post D1 (N=381;380;381;386) | 126 | 128 | 134 | 98 |
| G3 Loss App, Post D1 (N=381;380;381;386) | 6 | 3 | 1 | 1 |
| Any Drows, Post D2 (N=377;376;379;385) | 168 | 174 | 176 | 161 |
| G3 Drows, Post D2 (N=377;376;379;385) | 4 | 6 | 2 | 5 |
| Any Fever, Post D2 (N=377;376;379;385) | 169 | 156 | 138 | 142 |

| | | | | |
|--|-----|-----|-----|-----|
| G3 Fever, Post D2 (N=377;376;379;385) | 15 | 17 | 11 | 11 |
| Any Irr , Post D2 (N=377;376;379;385) | 215 | 197 | 217 | 193 |
| G3 Irr, Post D2 (N=377;376;379;385) | 18 | 16 | 20 | 12 |
| Any Loss App, Post D2 (N=377;376;379;385) | 118 | 112 | 111 | 120 |
| G3 Loss App, Post D2 (N=377;376;379;385) | 1 | 2 | 0 | 2 |
| Any Drows, Post D3 (N=373;373;370;375) | 115 | 126 | 117 | 107 |
| G3 Drows, Post D3 (N=373;373;370;375) | 2 | 2 | 1 | 3 |
| Any Fever, Post D3 (N=373;373;370;375) | 90 | 87 | 90 | 89 |
| G3 Fever, Post D3 (N=373;373;370;375) | 14 | 12 | 9 | 11 |
| Any Irr , Post D3 (N=373;373;370;375) | 162 | 150 | 158 | 138 |
| G3 Irr, Post D3 (N=373;373;370;375) | 9 | 13 | 3 | 7 |
| Any Loss App, Post D3 (N=373;373;370;375) | 95 | 83 | 89 | 96 |
| G3 Loss App, Post D3 (N=373;373;370;375) | 1 | 3 | 1 | 2 |
| Any Drows, AD (N=381;380;381;386) | 268 | 276 | 265 | 252 |
| G3 Drows, AD (N=381;380;381;386) | 13 | 15 | 10 | 13 |
| Any Fever, AD (N=381;380;381;386) | 247 | 258 | 223 | 218 |
| G3 Fever, AD (N=381;380;381;386) | 36 | 40 | 23 | 24 |
| Any Irr , AD (N=381;380;381;386) | 301 | 294 | 293 | 281 |
| G3 Irr, AD (N=381;380;381;386) | 49 | 40 | 38 | 31 |
| Any Loss App, AD (N=381;380;381;386) | 203 | 200 | 209 | 196 |
| G3 Loss App, AD (N=381;380;381;386) | 8 | 7 | 2 | 4 |

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

An AE is any untoward medical occurrence in a clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. "Any" is defined as an incidence of an unsolicited AE regardless of intensity or relationship to study vaccination. This endpoint concerns subjects with at least one vaccination dose documented. The 24 subjects from a center located in Germany (6 in each group) who were later eliminated and excluded from efficacy analyses due to protocol compliance following findings of a for cause audit were not taken into account in this analysis.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Within 31 days (Day 0-30) after each vaccination, across doses

| End point values | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group | Prevenar™ + Menitorix™ Group |
|-----------------------------|----------------------------------|---------------------------------|---------------------------------|------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 385 | 387 | 386 | 390 |
| Units: Subjects | | | | |
| Any unsolicited AE(s) | 144 | 142 | 144 | 153 |

Statistical analyses

No statistical analyses for this end point

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

| | |
|-----------------|--|
| End point title | Number of subjects with serious adverse events (SAEs) in vaccinated subjects |
|-----------------|--|

End point description:

An SAE is any untoward medical occurrence that: results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, or may evolve into one of the outcomes listed above. "Any" is defined as an incidence of a SAE regardless of intensity/severity. This endpoint concerns subjects with at least one vaccination dose documented at the exclusion of the 24 subjects from a center located in Germany (6 in each group) who were later eliminated and excluded from efficacy analyses due to protocol compliance following findings of a for cause audit.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Throughout the Active Phase of the study, from first vaccination at 6-16 weeks of age till approximately 7 months of age.

| End point values | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group | Prevenar™ + Menitorix™ Group |
|-----------------------------|----------------------------------|---------------------------------|---------------------------------|------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 385 | 387 | 386 | 390 |
| Units: Subjects | | | | |
| Any SAE(s) | 8 | 14 | 10 | 13 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serious adverse events (SAEs) in enrolled subjects who were eliminated from the study efficacy analyses

| | |
|-----------------|---|
| End point title | Number of subjects with serious adverse events (SAEs) in enrolled subjects who were eliminated from the study efficacy analyses |
|-----------------|---|

End point description:

An SAE is any untoward medical occurrence that: results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, or may evolve into one of the outcomes listed above. "Any" is defined as an incidence of a SAE regardless of intensity/severity. This endpoint concerns the 24 subjects from a center located in Germany (6 in each group) who were later eliminated from analyses due to protocol compliance following findings of a for cause audit.

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Throughout the Active Phase of the study, from first vaccination at 6-16 weeks of age till approximately 7 months of age. | |

| End point values | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group | Prevenar™ + Menitorix™ Group |
|-----------------------------|----------------------------------|---------------------------------|---------------------------------|------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 6 | 6 | 6 | 6 |
| Units: Subjects | | | | |
| Any SAE(s) | 0 | 1 | 0 | 0 |

Statistical analyses

No statistical analyses for this end point

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

| | |
|--|---|
| End point title | Number of subjects with serious adverse events (SAEs) |
| End point description: | |
| An SAE is any untoward medical occurrence that: results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, or may evolve into one of the outcomes listed above. "Any" is defined as an incidence of a SAE regardless of intensity/severity. This endpoint concerns all subjects enrolled in the study, that is, eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) and the 24 subjects from a center located in Germany (6 in each group) who were later eliminated from analyses due to protocol compliance following findings of a for cause audit. | |
| End point type | Secondary |
| End point timeframe: | |
| Throughout the entire study, from 1st vaccination at 6-16 weeks of age till the end of the ESFU Phase, when subjects reached approximately 12 months of age. | |

| End point values | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group | Prevenar™ + Menitorix™ Group |
|-----------------------------|----------------------------------|---------------------------------|---------------------------------|------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 391 | 393 | 392 | 396 |
| Units: Subjects | | | | |
| Any SAE(s) | 24 | 30 | 30 | 28 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations above or equal to (\geq) 0.20 microgram per liter ($\mu\text{g/mL}$)

| | |
|-----------------|--|
| End point title | Number of subjects with anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations above or equal to (\geq) 0.20 microgram per liter ($\mu\text{g/mL}$) |
|-----------------|--|

End point description:

The number of subjects with anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations (Anti-1, -4, -5, -6B, -7F, -9V, -14, -18C, -19F and -23F) above or equal to \geq 0.20 $\mu\text{g/mL}$ was tabulated. The seroprotection and seropositivity cut-off values for the assay were \geq 0.20 $\mu\text{g/mL}$ and \geq 0.05 $\mu\text{g/mL}$, respectively. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At Month 5 (M5), aka one month after the administration of the third dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

| End point values | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group | Prevenar™ + Menitorix™ Group |
|-------------------------------------|----------------------------------|---------------------------------|---------------------------------|------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 169 | 175 | 173 | 170 |
| Units: Subjects | | | | |
| Anti 1, at M5 (N=169;174;173;170) | 163 | 170 | 161 | 1 |
| Anti 4, at M5 (N=169;174;173;170) | 169 | 173 | 170 | 170 |
| Anti-5, at M5 (N=169;174;173;168) | 169 | 174 | 171 | 4 |
| Anti 6B, at M5 (N=169;175;173;169) | 159 | 155 | 151 | 157 |
| Anti 7F, at M5 (N=169;175;173;169) | 169 | 174 | 171 | 5 |
| Anti 9V, at M5 (N=169;175;173;169) | 167 | 171 | 170 | 167 |
| Anti 14, at M5 (N=169;175;173;169) | 169 | 175 | 173 | 168 |
| Anti 18C, at M5 (N=169;175;173;169) | 167 | 173 | 172 | 167 |
| Anti 19F, at M5 (N=169;175;173;170) | 166 | 174 | 171 | 170 |
| Anti 23F, at M5 (N=169;175;173;169) | 162 | 168 | 160 | 159 |

Statistical analyses

Secondary: Anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations

| | |
|-----------------|---|
| End point title | Anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations |
|-----------------|---|

End point description:

Anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations (Anti-1, -4, -5, -6B, -7F, -9V, -14, -18C, -19F and -23F) were calculated, expressed as geometric mean concentrations (GMCs) and tabulated. The seropositivity cut-off for the assay was ≥ 0.05 microgram per millilitre ($\mu\text{g/mL}$). Antibody concentrations or titres < 0.05 $\mu\text{g/mL}$ were given an arbitrary value of half the cut-off for the purpose of GMC calculation. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At Month 5 (M5), aka one month after the administration of the third dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

| End point values | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group | Prevenar™ + Menitorix™ Group |
|--|----------------------------------|---------------------------------|---------------------------------|------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 169 | 175 | 173 | 170 |
| Units: $\mu\text{g/mL}$ | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti 1, at M5 (N=169;174;173;170) | 1.17 (1.03 to 1.33) | 1.09 (0.96 to 1.24) | 1 (0.86 to 1.15) | 0.03 (0.03 to 0.03) |
| Anti 4, at M5 (N=169;174;173;170) | 1.88 (1.7 to 2.09) | 1.96 (1.76 to 2.19) | 1.7 (1.52 to 1.92) | 2.78 (2.46 to 3.14) |
| Anti-5, at M5 (N=169;174;173;168) | 1.96 (1.78 to 2.17) | 1.87 (1.69 to 2.08) | 1.69 (1.49 to 1.91) | 0.03 (0.03 to 0.04) |
| Anti 6B, at M5 (N=169;175;173;169) | 0.96 (0.82 to 1.12) | 0.85 (0.72 to 1.01) | 0.71 (0.59 to 0.86) | 1.32 (1.12 to 1.57) |
| Anti 7F, at M5 (N=169;175;173;169) | 2.82 (2.54 to 3.14) | 2.57 (2.32 to 2.86) | 2.25 (1.98 to 2.55) | 0.04 (0.03 to 0.04) |
| Anti 9V, at M5 (N=169;175;173;169) | 1.77 (1.58 to 2) | 1.72 (1.52 to 1.95) | 1.58 (1.4 to 1.77) | 3.17 (2.75 to 3.64) |
| Anti 14, at M5 (N=169;175;173;169) | 3.75 (3.25 to 4.31) | 3.79 (3.37 to 4.26) | 3.36 (2.91 to 3.88) | 5.97 (5.05 to 7.07) |
| Anti 18C, at M5 (N=169;175;173;169) | 2.43 (2.07 to 2.84) | 3.92 (3.38 to 4.54) | 2.34 (2.01 to 2.71) | 3.01 (2.65 to 3.42) |
| Anti 19F, at M5 (N=169;175;173;170) | 4.93 (4.28 to 5.68) | 4.71 (4.09 to 5.42) | 3.81 (3.32 to 4.37) | 2.56 (2.29 to 2.86) |
| Anti 23F, at M5 (N=169;175;173;169) | 1.3 (1.13 to 1.49) | 1.2 (1.02 to 1.4) | 0.96 (0.82 to 1.13) | 2.46 (2.04 to 2.98) |

Statistical analyses

Secondary: Opsonophagocytic activity (OPA) titers against pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F

| | |
|-----------------|---|
| End point title | Opsonophagocytic activity (OPA) titers against pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F |
|-----------------|---|

End point description:

OPA titers against pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F (OPA Anti-1, -4, -5, -6B, -7F, -9V, -14, -18C, -19F and -23F) were calculated, expressed as geometric mean titers (GMTs) and tabulated. The seropositivity cut-off for the assay was ≥ 8 . Antibody titers < 8 were given an arbitrary value of half the cut-off for the purpose of GMT calculation. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At Month 5 (M5), aka one month after the administration of the third dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

| End point values | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group | Prevenar™ + Menitorix™ Group |
|--|----------------------------------|---------------------------------|---------------------------------|------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 162 | 168 | 161 | 156 |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| OPA Anti-1, at M5 (N=162;168;161;156) | 23.9 (17.9 to 32) | 18.8 (14.4 to 24.4) | 19.7 (14.9 to 26.1) | 4.2 (3.9 to 4.5) |
| OPA Anti-4, at M5 (N=154;159;159;154) | 697.4 (617.8 to 787.3) | 755.6 (660.9 to 863.7) | 669.8 (553.8 to 810) | 926.2 (779.5 to 1100.4) |
| OPA Anti-5, at M5 (N=153;163;159;153) | 91.7 (72.7 to 115.7) | 71.4 (56.5 to 90.4) | 77.4 (61 to 98.2) | 4.2 (4 to 4.5) |
| OPA Anti-6B, at M5 (N=148;150;148;151) | 459.1 (334.2 to 630.8) | 404.6 (287.7 to 569.1) | 354.2 (243.4 to 515.3) | 1575.3 (1230.8 to 2016) |
| OPA Anti-7F, at M5 (N=149;164;158;138) | 2513.3 (2106.1 to 2999.3) | 2821.3 (2297.9 to 3463.9) | 2290.5 (1802.3 to 2910.9) | 8.7 (6.3 to 11.9) |
| OPA Anti-9V, at M5 (N=153;153;155;150) | 1005.6 (825.3 to 1225.2) | 1108.8 (905.9 to 1357.1) | 1122.6 (938.9 to 1342.3) | 1305 (1046.3 to 1627.6) |
| OPA Anti-14, at M5 (N=154;167;160;154) | 797.8 (655.3 to 971.2) | 879 (709.1 to 1089.5) | 779.9 (628.1 to 968.3) | 1539.4 (1230.2 to 1926.2) |
| OPA Anti-18C, at M5 (N=155;163;157;149) | 174.9 (144.1 to 212.3) | 282.8 (234.7 to 340.8) | 142.7 (113.8 to 179.1) | 212.8 (174.9 to 258.9) |
| OPA Anti-19F, at M5 (N=157;165;159;147) | 387.5 (305 to 492.2) | 298.4 (230.3 to 386.7) | 261 (200.9 to 339) | 52 (40.8 to 66.4) |
| OPA Anti-23F, at M5 (N=146;156;146;148) | 1066 (811.9 to 1399.6) | 1219.6 (930.7 to 1598.2) | 880.7 (633.1 to 1225.1) | 5469.2 (4410.2 to 6782.6) |

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody concentrations to protein D (Anti-PD)

| | |
|-----------------|--|
| End point title | Antibody concentrations to protein D (Anti-PD) |
|-----------------|--|

End point description:

Anti-protein D (Anti-PD) antibody concentrations by Enzyme-Linked Immunosorbent Assay (ELISA) were calculated, expressed as geometric mean concentrations (GMCs) in ELISA unit per milli-liter (EL.U/mL) and tabulated. The seropositivity cut-off for the assay was ≥ 100 EL.U/mL. Antibody concentrations < 100 EL.U/mL were given an arbitrary value of half the cut-off for the purpose of GMC calculation. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At Month 5 (M5), aka one month after the administration of the third dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

| End point values | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group | Prevenar™ + Menitorix™ Group |
|--|----------------------------------|---------------------------------|---------------------------------|------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 168 | 174 | 173 | 163 |
| Units: EL.U/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti-PD, at M5 | 2114 (1847.6 to 2418.8) | 1715.5 (1494.9 to 1968.7) | 1726.7 (1493.3 to 1996.7) | 72.3 (64.5 to 81.1) |

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-pertussis toxoid (Anti-PT), anti- filamentous haemagglutinin (Anti-FHA) and anti-pertactin (Anti-PRN) antibody concentrations

| | |
|-----------------|--|
| End point title | Anti-pertussis toxoid (Anti-PT), anti- filamentous haemagglutinin (Anti-FHA) and anti-pertactin (Anti-PRN) antibody concentrations |
|-----------------|--|

End point description:

Anti-PT, Anti-FHA and Anti-PRN concentrations measured by Enzyme-Linked Immunosorbent Assay (ELISA) were calculated, expressed as geometric mean concentrations (GMCs) in ELISA unit per milli-liter (EL.U/mL) and tabulated. The seropositivity cut-off for the assay was ≥ 5 EL.U/mL. Antibody concentrations < 5 EL.U/mL were given an arbitrary value of half the cut-off for the purpose of GMC calculation. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At Month 5 (M5), aka one month after the administration of the third dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

| End point values | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group | Prevenar™ + Menitorix™ Group |
|--|----------------------------------|---------------------------------|---------------------------------|------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 168 | 174 | 173 | 168 |
| Units: EL.U/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti-PT, at M5 (N=168;174;172;166) | 38.4 (34.9 to 42.4) | 43.1 (39.1 to 47.5) | 42.2 (38.3 to 46.6) | 43.2 (39.6 to 47.1) |
| Anti-FHA, at M5 (N=168;174;173;168) | 162.6 (147.1 to 179.7) | 184.3 (165.8 to 204.9) | 189.2 (172.8 to 207.3) | 191.2 (174 to 210.2) |
| Anti-PRN, at M5 (N=168;174;173;168) | 95.1 (84.4 to 107.2) | 107.5 (94 to 123) | 99.9 (87.4 to 114.2) | 110.5 (97.5 to 125.1) |

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-diphtheria (Anti-D) and anti-tetanus toxoids (Anti-TT) antibody concentrations

| | |
|-----------------|---|
| End point title | Anti-diphtheria (Anti-D) and anti-tetanus toxoids (Anti-TT) antibody concentrations |
|-----------------|---|

End point description:

Anti-D and Anti-TT antibody concentrations were calculated, expressed as geometric mean concentrations (GMCs), in International units per milliliter (IU/mL), and tabulated. The seropositivity cut-off for the assay was ≥ 0.1 IU/mL. Antibody concentrations < 0.1 IU/mL were given an arbitrary value of half the cut-off for the purpose of GMC calculation. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At Month 5 (M5), aka one month after the administration of the third dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

| End point values | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group | Prevenar™ + Menitorix™ Group |
|--|----------------------------------|---------------------------------|---------------------------------|------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 169 | 175 | 173 | 169 |
| Units: IU/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti-D, at M5 | 2.808 (2.521 to 3.127) | 2.263 (1.975 to 2.593) | 2.436 (2.137 to 2.778) | 2.615 (2.316 to 2.952) |
| Anti-TT, at M5 | 3.522 (3.185 to 3.896) | 5.259 (4.828 to 5.729) | 4.508 (4.134 to 4.916) | 3.566 (3.265 to 3.895) |

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-polyribosyl-ribitol-phosphate (Anti-PRP) antibody concentrations

| | |
|-----------------|---|
| End point title | Anti-polyribosyl-ribitol-phosphate (Anti-PRP) antibody concentrations |
|-----------------|---|

End point description:

Anti-PRP antibody concentrations were calculated, expressed as geometric mean concentrations (GMCs), in microgram per milliliter (µg/mL), and tabulated. The seroprotection cut-off for the assay for the purpose of this endpoint was ≥ 0.15 µg/mL. Antibody concentrations < 0.15 µg/mL were given an arbitrary value of half the cut-off for the purpose of GMC calculation. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At Month 4 (M4), aka 2 months after the administration of the 2nd dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

| End point values | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group | Prevenar™ + Menitorix™ Group |
|--|----------------------------------|---------------------------------|---------------------------------|------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 171 | 178 | 174 | 172 |
| Units: µg/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti-PRP, at M4 | 1.429 (1.124 to 1.816) | 2.704 (2.212 to 3.306) | 1.99 (1.575 to 2.514) | 1.591 (1.249 to 2.026) |

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-polyribosyl-ribitol-phosphate (Anti-PRP) antibody concentrations

| | |
|-----------------|---|
| End point title | Anti-polyribosyl-ribitol-phosphate (Anti-PRP) antibody concentrations |
|-----------------|---|

End point description:

Anti-PRP antibody concentrations were calculated, expressed as geometric mean concentrations (GMCs), in microgram per milliliter ($\mu\text{g/mL}$), and tabulated. The seroprotection cut-off for the assay for the purpose of this endpoint was $\geq 0.15 \mu\text{g/mL}$. Antibody concentrations $< 0.15 \mu\text{g/mL}$ were given an arbitrary value of half the cut-off for the purpose of GMC calculation. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At Month 5 (M5), aka one month after the administration of the third dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

| End point values | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group | Prevenar™ + Menitorix™ Group |
|--|----------------------------------|---------------------------------|---------------------------------|------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 168 | 174 | 172 | 170 |
| Units: $\mu\text{g/mL}$ | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti-PRP, at M5 | 4.343 (3.556 to 5.304) | 6.708 (5.762 to 7.81) | 13.746 (11.406 to 16.567) | 10.947 (9.165 to 13.077) |

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-hepatitis B surface antigen (HBs) antibody concentrations

| | |
|-----------------|--|
| End point title | Anti-hepatitis B surface antigen (HBs) antibody concentrations |
|-----------------|--|

End point description:

Anti-HBs antibody concentrations were calculated, expressed as geometric mean concentrations (GMCs), in milli-International unit per milliliter (IU/mL), and tabulated per country (Germany, Poland, Spain) and in total – across all countries. The seropositivity cut-off for the assay was $\geq 10 \text{ mIU/mL}$. Antibody concentrations $< 10 \text{ mIU/mL}$ were given an arbitrary value of half the cut-off for the purpose of GMC calculation. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At Month 5 (M5), aka one month after the administration of the third dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

| End point values | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group | Prevenar™ + Menitorix™ Group |
|--|----------------------------------|---------------------------------|---------------------------------|------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 62 | 80 | 89 | 64 |
| Units: mIU/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti-HBs, In Germany, at M5 (N=12;17;16;9) | 516 (289 to 921.2) | 550.2 (246.4 to 1228.6) | 533.9 (222.3 to 1282.2) | 464.9 (262 to 825.1) |
| Anti-HBs, In Poland, at M5 (N=24;34;41;25) | 1100.7 (819.9 to 1477.7) | 1037.1 (868.4 to 1238.7) | 925.4 (662.6 to 1292.3) | 739.9 (542.3 to 1009.7) |
| Anti-HBs, In Spain, at M5 (N=26;29;32;30) | 863.5 (609.8 to 1222.8) | 684 (384.2 to 1218) | 913.1 (655.4 to 1272) | 908 (664.4 to 1241) |
| Anti-HBs, In Total, at M5 (N=62;80;89;64) | 858.6 (692.9 to 1063.9) | 779.5 (594.3 to 1022.4) | 834.2 (655.4 to 1061.8) | 762.9 (622.9 to 934.4) |

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-polio type 1, 2 and 3 (Anti-Polio 1, 2 and 3) antibody titers

| | |
|-----------------|--|
| End point title | Anti-polio type 1, 2 and 3 (Anti-Polio 1, 2 and 3) antibody titers |
|-----------------|--|

End point description:

Anti-Polio 1, 2 and 3 antibody titers were calculated, expressed as geometric mean titers (GMTs) and tabulated. The seroprotection cut-off for the assay was ≥ 8 . Antibody titers < 8 were given an arbitrary value of half the cut-off for the purpose of GMT calculation. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At Month 5 (M5), aka one month after the administration of the third dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

| End point values | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group | Prevenar™ + Menitorix™ Group |
|--|----------------------------------|---------------------------------|---------------------------------|------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 39 | 44 | 49 | 41 |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti-Polio 1, at M5 (N=39;44;49;41) | 284.9 (191.6 to 423.6) | 427.2 (301.1 to 606.3) | 454.2 (319.6 to 645.4) | 371.3 (247 to 558.1) |
| Anti-Polio 2, at M5 (N=31;42;46;32) | 327.1 (196.7 to 543.9) | 251.8 (176.2 to 359.9) | 263.8 (170.8 to 407.6) | 298.2 (184.8 to 481.3) |

| | | | | |
|-------------------------------------|------------------------|------------------------|----------------------|-------------------------|
| Anti-Polio 3, at M5 (N=34;36;49;38) | 572.8 (361.7 to 907.3) | 608.9 (413.6 to 896.5) | 590 (402.7 to 864.5) | 666.5 (410.6 to 1081.7) |
|-------------------------------------|------------------------|------------------------|----------------------|-------------------------|

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-polysaccharide C (Anti-PSC) antibody concentrations ≥ 2.0 micrograms per milliliter ($\mu\text{g/mL}$)

| | |
|-----------------|--|
| End point title | Number of subjects with anti-polysaccharide C (Anti-PSC) antibody concentrations ≥ 2.0 micrograms per milliliter ($\mu\text{g/mL}$) |
|-----------------|--|

End point description:

The number of subjects with Anti-PSC above or equal to $\geq 2.0 \mu\text{g/mL}$ was tabulated. The seroprotection and seropositivity cut-off values for the assay were $\geq 2.0 \mu\text{g/mL}$ and $\geq 0.30 \mu\text{g/mL}$, respectively. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At Month 4 (M4), aka 2 months after the administration of the 2nd dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

| End point values | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group | Prevenar™ + Menitorix™ Group |
|--|----------------------------------|---------------------------------|---------------------------------|------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 170 | 178 | 174 | 171 |
| Units: Subjects | | | | |
| Anti PSC $\geq 2.0 \mu\text{g/mL}$, at M4 (N=170;178;174;171) | 163 | 172 | 159 | 154 |

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-polysaccharide C (Anti-PSC) antibody concentrations

| | |
|-----------------|--|
| End point title | Anti-polysaccharide C (Anti-PSC) antibody concentrations |
|-----------------|--|

End point description:

Anti-PSC antibody concentrations were calculated, expressed as geometric mean concentrations (GMCs), in microgram per milliliter ($\mu\text{g/mL}$), and tabulated. The seropositivity cut-off for the assay was $\geq 0.30 \mu\text{g/mL}$. Antibody concentrations $< 0.30 \mu\text{g/mL}$ were given an arbitrary value of half the cut-off for the purpose of GMC calculation. Seroprotection status, defined as: Anti-PRP antibody concentrations ≥ 0.15 and $\geq 1.0 \mu\text{g/mL}$. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available

for antibodies against at least one study vaccine antigen component after vaccination.

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| At Month 4 (M4), aka 2 months after the administration of the 2nd dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines. | |

| End point values | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group | Prevenar™ + Menitorix™ Group |
|--|----------------------------------|---------------------------------|---------------------------------|------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 170 | 178 | 174 | 171 |
| Units: µg/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti-PSC, at M4 (N=170;178;174;171) | 5.96 (5.42 to 6.57) | 7.99 (7.28 to 8.77) | 6.1 (5.47 to 6.8) | 5.64 (5.05 to 6.3) |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-polysaccharide C (Anti-PSC) antibody concentrations ≥ 2.0 microgram per milliliter (µg/mL)

| | |
|-----------------|--|
| End point title | Number of subjects with anti-polysaccharide C (Anti-PSC) antibody concentrations ≥ 2.0 microgram per milliliter (µg/mL) |
|-----------------|--|

End point description:

The number of subjects with Anti-PSC above or equal to ≥ 2.0 µg/mL was tabulated. The seroprotection and seropositivity cut-off values for the assay were ≥ 2.0 µg/mL and ≥ 0.30 µg/mL, respectively. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| At Month 5 (M5), aka one month after the administration of the third dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines. | |

| End point values | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group | Prevenar™ + Menitorix™ Group |
|--|----------------------------------|---------------------------------|---------------------------------|------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 168 | 174 | 173 | 169 |
| Units: Subjects | | | | |
| Anti-PSC ≥ 2.0 µg/mL, at M5 (N=168;174;173;169) | 138 | 160 | 166 | 161 |

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-polysaccharide C (Anti-PSC) antibody concentrations

| | |
|-----------------|--|
| End point title | Anti-polysaccharide C (Anti-PSC) antibody concentrations |
|-----------------|--|

End point description:

Anti-PSC antibody concentrations were calculated, expressed as geometric mean concentrations (GMCs), in microgram per milliliter ($\mu\text{g/mL}$), and tabulated. The seropositivity cut-off for the assay was $\geq 0.30 \mu\text{g/mL}$. Antibody concentrations $< 0.30 \mu\text{g/mL}$ were given an arbitrary value of half the cut-off for the purpose of GMC calculation. Seroprotection status, defined as: Anti-PRP antibody concentrations ≥ 0.15 and $\geq 1.0 \mu\text{g/mL}$. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At Month 5 (M5), aka one month after the administration of the third dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

| End point values | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group | Prevenar™ + Menitorix™ Group |
|--|----------------------------------|---------------------------------|---------------------------------|------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 168 | 174 | 173 | 169 |
| Units: $\mu\text{g/mL}$ | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti-PSC, at M5 (N=168;174;173;169) | 4.08 (3.64 to 4.56) | 5.64 (5.13 to 6.2) | 7.27 (6.59 to 8.01) | 6.17 (5.58 to 6.81) |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serum bactericidal assay (performed using baby rabbit complement) for Neisseria meningitidis serogroups C (rSBA-MenC) antibody titers ≥ 128

| | |
|-----------------|--|
| End point title | Number of subjects with serum bactericidal assay (performed using baby rabbit complement) for Neisseria meningitidis serogroups C (rSBA-MenC) antibody titers ≥ 128 |
|-----------------|--|

End point description:

The number of subjects with rSBA-MenC) antibody titres above or equal to ≥ 128 was tabulated. The seroprotection cut-off value for the assay was ≥ 8 . Analysis for this endpoint was performed on eligible

subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| At Month 4 (M4), aka 2 months after the administration of the 2nd dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines. | |

| End point values | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group | Prevenar™ + Menitorix™ Group |
|--|----------------------------------|---------------------------------|---------------------------------|------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 165 | 177 | 168 | 166 |
| Units: Subjects | | | | |
| rSBA-MenC ≥ 128, at M4 (N=165;177;168;166) | 160 | 172 | 150 | 146 |

Statistical analyses

No statistical analyses for this end point

Secondary: Serum bactericidal assay (performed using baby rabbit complement) for *Neisseria meningitidis* serogroups C (rSBA-MenC) antibody titers

| | |
|-----------------|--|
| End point title | Serum bactericidal assay (performed using baby rabbit complement) for <i>Neisseria meningitidis</i> serogroups C (rSBA-MenC) antibody titers |
|-----------------|--|

End point description:

rSBA-MenC antibody titres were calculated, expressed as geometric mean titers (GMTs) and tabulated. The seroprotection cut-off value for the assay was ≥ 8 . Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| At Month 4 (M4), aka 2 months after the administration of the 2nd dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines. | |

| End point values | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group | Prevenar™ + Menitorix™ Group |
|--|----------------------------------|---------------------------------|---------------------------------|------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 165 | 177 | 168 | 166 |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |

| | | | | |
|---|----------------------------|------------------------------|---------------------------|---------------------------|
| rSBA-MenC, at M4 (N=165;177;168;166) | 1299.8 (1082 to 1561.5) | 1474.2 (1263.3 to 1720.4) | 501.8 (410.3 to 613.6) | 480.4 (399.1 to 578.2) |
|---|----------------------------|------------------------------|---------------------------|---------------------------|

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serum bactericidal assay (performed using baby rabbit complement) for *Neisseria meningitidis* serogroups C (rSBA-MenC) antibody titers ≥ 128

| | |
|-----------------|---|
| End point title | Number of subjects with serum bactericidal assay (performed using baby rabbit complement) for <i>Neisseria meningitidis</i> serogroups C (rSBA-MenC) antibody titers ≥ 128 |
|-----------------|---|

End point description:

The number of subjects with rSBA-MenC) antibody titres above or equal to ≥ 128 was tabulated. The seroprotection cut-off value for the assay was ≥ 8 . Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At Month 5 (M5), aka one month after the administration of the third dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

| End point values | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group | Prevenar™ + Menitorix™ Group |
|---|-------------------------------------|------------------------------------|------------------------------------|---------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 126 | 138 | 137 | 120 |
| Units: Subjects | | | | |
| rSBA-MenC ≥ 128 , at M5 (N=126;138;137;120) | 118 | 134 | 133 | 114 |

Statistical analyses

No statistical analyses for this end point

Secondary: Serum bactericidal assay (performed using baby rabbit complement) for *Neisseria meningitidis* serogroups C (rSBA-MenC) antibody titers

| | |
|-----------------|--|
| End point title | Serum bactericidal assay (performed using baby rabbit complement) for <i>Neisseria meningitidis</i> serogroups C (rSBA-MenC) antibody titers |
|-----------------|--|

End point description:

rSBA-MenC antibody titres were calculated, expressed as geometric mean titers (GMTs) and tabulated. The seroprotection cut-off value for the assay was ≥ 8 . Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of

subjects with serious adverse events (SAEs) in vaccinated subjects” for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At Month 5 (M5), aka one month after the administration of the third dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

| End point values | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group | Prevenar™ + Menitorix™ Group |
|--|----------------------------------|---------------------------------|---------------------------------|------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 126 | 138 | 137 | 120 |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| rSBA-MenC, at M5 (N=126;138;137;120) | 665.2 (528.8 to 836.8) | 1152.6 (958.4 to 1386.3) | 1590.9 (1298.5 to 1949.1) | 1207.7 (964.4 to 1512.3) |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited symptoms and unsolicited AEs: within 4 and 31 days post vaccination, across doses, respectively. SAEs: Between Dose 1 at 6-16 weeks of age till the end of the ESFU Phase, when subjects reached approximately 12 months of age.

Adverse event reporting additional description:

Occurrences of reported AEs (all/related) were not available and are encoded as equal to the number of subjects affected. Note that safety events reported below include the SAEs reported for the 24 subjects from a center located in Germany (6 in each group) who were excluded from efficacy analyses due to protocol compliance issues.

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

| | |
|--------------------|--------|
| Dictionary name | MedDRA |
| Dictionary version | 11.0 |

Reporting groups

| | |
|-----------------------|----------------------------------|
| Reporting group title | GSK 1024850A + Meningitec™ Group |
|-----------------------|----------------------------------|

Reporting group description:

Subjects were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (also referred to as 10Pn-PD-DiT or 10Pn vaccine) co-administered with Infanrix™ hexa (also referred to as DTPa-HBV-IPV/Hib). In addition, subjects also received Wyeth's Men-C conjugate vaccine (Meningitec™, also referred to as Men vaccine) at 2 and 4 months of age. For subjects in Poland and to comply with national recommendations, subjects were also offered a third dose of Meningitec™ at approximately 7 months of age, after the blood sampling performed at that time point. All vaccines were administered intramuscularly (IM), 10Pn in the right thigh, Infanrix™ hexa in the upper left thigh and Meningitec™ in the lower left thigh.

| | |
|-----------------------|---------------------------------|
| Reporting group title | GSK 1024850A + NeisVac-C™ Group |
|-----------------------|---------------------------------|

Reporting group description:

Subjects were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (also referred to as 10Pn-PD-DiT or 10Pn vaccine) co-administered with Infanrix™ hexa (also referred to as DTPa-HBV-IPV/Hib). In addition, subjects also received Baxter's Men-C conjugate vaccine (NeisVac-C™, also referred to as Neis vaccine) at 2 and 4 months of age. For subjects in Poland and to comply with national recommendations, subjects were also offered a third dose of NeisVac-C™, at approximately 7 months of age, after the blood sampling performed at that time point. All vaccines were administered intramuscularly (IM), 10Pn in the right thigh, Infanrix™ hexa in the upper left thigh and NeisVac-C™, in the lower left thigh.

| | |
|-----------------------|---------------------------------|
| Reporting group title | GSK 1024850A + Menitorix™ Group |
|-----------------------|---------------------------------|

Reporting group description:

The Group is also referred to as the 10Pn-PD-DiT + Hib-MenC Group and included subjects who were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (also referred to as 10Pn-PD-DiT or 10Pn vaccine) co-administered with Infanrix™ pent (also referred to as DTPa-HBV-IPV) and with Menitorix™ (HibMenC). All vaccines were administered intramuscularly (IM), 10Pn in the right thigh, Infanrix™ penta in the upper left thigh and Menitorix™ in the lower left thigh.

| | |
|-----------------------|------------------------------|
| Reporting group title | Prevenar™ + Menitorix™ Group |
|-----------------------|------------------------------|

Reporting group description:

The Group is also referred to as the Prevenar Group and included Subjects were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of Wyeth's 7-valent pneumococcal conjugate vaccine (Prevenar™ or 7Pn) co-administered with Infanrix™ penta and Menitorix™, GSK Biologicals' combined Hib-MenC vaccine (also referred to as HibMenC). All vaccines were administered intramuscularly (IM), Prevenar™ in the right thigh, Infanrix™ penta in the upper left thigh and Menitorix™, in the lower left thigh.

| Serious adverse events | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group |
|---|-------------------------------------|------------------------------------|------------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 24 / 391 (6.14%) | 30 / 393 (7.63%) | 30 / 392 (7.65%) |
| 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) | | | |
| Haemangioma | | | |
| subjects affected / exposed | 0 / 391 (0.00%) | 0 / 393 (0.00%) | 0 / 392 (0.00%) |
| 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 / 391 (0.00%) | 1 / 393 (0.25%) | 1 / 392 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Hypersensitivity | | | |
| subjects affected / exposed | 1 / 391 (0.26%) | 0 / 393 (0.00%) | 0 / 392 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| Genital labial adhesions | | | |
| subjects affected / exposed | 0 / 391 (0.00%) | 0 / 393 (0.00%) | 1 / 392 (0.26%) |
| 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 | | | |
| Bronchitis chronic | | | |
| subjects affected / exposed | 3 / 391 (0.77%) | 3 / 393 (0.76%) | 1 / 392 (0.26%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Apnoea | | | |
| subjects affected / exposed | 0 / 391 (0.00%) | 0 / 393 (0.00%) | 1 / 392 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Allergic bronchitis | | | |
| subjects affected / exposed | 1 / 391 (0.26%) | 0 / 393 (0.00%) | 0 / 392 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Wheezing | | | |
| subjects affected / exposed | 0 / 391 (0.00%) | 1 / 393 (0.25%) | 0 / 392 (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 |
| Injury, poisoning and procedural complications | | | |
| Fracture | | | |
| subjects affected / exposed | 1 / 391 (0.26%) | 0 / 393 (0.00%) | 0 / 392 (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 |
| Concussion | | | |
| subjects affected / exposed | 0 / 391 (0.00%) | 0 / 393 (0.00%) | 1 / 392 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 391 (0.00%) | 0 / 393 (0.00%) | 0 / 392 (0.00%) |
| 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 | | | |
| Convulsion | | | |
| subjects affected / exposed | 0 / 391 (0.00%) | 0 / 393 (0.00%) | 1 / 392 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile convulsion | | | |
| subjects affected / exposed | 0 / 391 (0.00%) | 0 / 393 (0.00%) | 1 / 392 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 391 (0.26%) | 0 / 393 (0.00%) | 0 / 392 (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 |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 0 / 391 (0.00%) | 0 / 393 (0.00%) | 1 / 392 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 1 / 391 (0.26%) | 0 / 393 (0.00%) | 0 / 392 (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 |
| Gastroesophageal reflux disease | | | |
| subjects affected / exposed | 1 / 391 (0.26%) | 0 / 393 (0.00%) | 1 / 392 (0.26%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dyspepsia | | | |
| subjects affected / exposed | 1 / 391 (0.26%) | 0 / 393 (0.00%) | 0 / 392 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enteritis | | | |
| subjects affected / exposed | 1 / 391 (0.26%) | 0 / 393 (0.00%) | 0 / 392 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastritis | | | |
| subjects affected / exposed | 1 / 391 (0.26%) | 0 / 393 (0.00%) | 0 / 392 (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 |
| Hepatobiliary disorders | | | |
| Hepatosplenomegaly | | | |
| subjects affected / exposed | 0 / 391 (0.00%) | 1 / 393 (0.25%) | 0 / 392 (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 |
| Skin and subcutaneous tissue disorders | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| Dermatitis atopic | | | |
| subjects affected / exposed | 0 / 391 (0.00%) | 0 / 393 (0.00%) | 1 / 392 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urticaria | | | |
| subjects affected / exposed | 1 / 391 (0.26%) | 0 / 393 (0.00%) | 0 / 392 (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 | 0 / 391 (0.00%) | 0 / 393 (0.00%) | 1 / 392 (0.26%) |
| 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 and urinary disorders | | | |
| Cystitis noninfective | | | |
| subjects affected / exposed | 0 / 391 (0.00%) | 1 / 393 (0.25%) | 0 / 392 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Rickets | | | |
| subjects affected / exposed | 1 / 391 (0.26%) | 0 / 393 (0.00%) | 0 / 392 (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 | | | |
| Bronchitis | | | |
| subjects affected / exposed | 3 / 391 (0.77%) | 2 / 393 (0.51%) | 2 / 392 (0.51%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 3 / 391 (0.77%) | 6 / 393 (1.53%) | 1 / 392 (0.26%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 6 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract infection | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 391 (0.00%) | 4 / 393 (1.02%) | 2 / 392 (0.51%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchiolitis | | | |
| subjects affected / exposed | 2 / 391 (0.51%) | 2 / 393 (0.51%) | 3 / 392 (0.77%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 2 / 391 (0.51%) | 3 / 393 (0.76%) | 8 / 392 (2.04%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | 0 / 8 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchopneumonia | | | |
| subjects affected / exposed | 4 / 391 (1.02%) | 1 / 393 (0.25%) | 4 / 392 (1.02%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 391 (0.00%) | 2 / 393 (0.51%) | 1 / 392 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abscess of eyelid | | | |
| subjects affected / exposed | 0 / 391 (0.00%) | 0 / 393 (0.00%) | 0 / 392 (0.00%) |
| 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 escherichia coli | | | |
| subjects affected / exposed | 0 / 391 (0.00%) | 1 / 393 (0.25%) | 0 / 392 (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 salmonella | | | |
| subjects affected / exposed | 1 / 391 (0.26%) | 1 / 393 (0.25%) | 0 / 392 (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 |
| Pharyngitis | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 391 (0.00%) | 3 / 393 (0.76%) | 0 / 392 (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 |
| Pneumococcal sepsis | | | |
| subjects affected / exposed | 0 / 391 (0.00%) | 1 / 393 (0.25%) | 0 / 392 (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 |
| Pyelonephritis acute | | | |
| subjects affected / exposed | 0 / 391 (0.00%) | 1 / 393 (0.25%) | 1 / 392 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus bronchiolitis | | | |
| subjects affected / exposed | 1 / 391 (0.26%) | 1 / 393 (0.25%) | 1 / 392 (0.26%) |
| 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 rotavirus | | | |
| subjects affected / exposed | 0 / 391 (0.00%) | 2 / 393 (0.51%) | 1 / 392 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchospasm | | | |
| subjects affected / exposed | 0 / 391 (0.00%) | 3 / 393 (0.76%) | 1 / 392 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis norovirus | | | |
| subjects affected / exposed | 0 / 391 (0.00%) | 1 / 393 (0.25%) | 0 / 392 (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 / 391 (0.00%) | 0 / 393 (0.00%) | 0 / 392 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infectious mononucleosis | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 391 (0.00%) | 0 / 393 (0.00%) | 0 / 392 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 391 (0.00%) | 1 / 393 (0.25%) | 0 / 392 (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 |
| Kawasaki's disease | | | |
| subjects affected / exposed | 1 / 391 (0.26%) | 0 / 393 (0.00%) | 0 / 392 (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 |
| Laryngitis | | | |
| subjects affected / exposed | 1 / 391 (0.26%) | 0 / 393 (0.00%) | 0 / 392 (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 |
| Measles | | | |
| subjects affected / exposed | 0 / 391 (0.00%) | 1 / 393 (0.25%) | 0 / 392 (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 |
| Meningitis viral | | | |
| subjects affected / exposed | 0 / 391 (0.00%) | 0 / 393 (0.00%) | 1 / 392 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media | | | |
| subjects affected / exposed | 1 / 391 (0.26%) | 0 / 393 (0.00%) | 0 / 392 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 391 (0.00%) | 0 / 393 (0.00%) | 0 / 392 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pseudocroup | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 391 (0.00%) | 0 / 393 (0.00%) | 1 / 392 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 1 / 391 (0.26%) | 0 / 393 (0.00%) | 0 / 392 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 391 (0.00%) | 1 / 393 (0.25%) | 1 / 392 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 391 (0.00%) | 0 / 393 (0.00%) | 1 / 392 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Amino acid metabolism disorder | | | |
| subjects affected / exposed | 1 / 391 (0.26%) | 0 / 393 (0.00%) | 0 / 392 (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 |
| Hyponatraemia | | | |
| subjects affected / exposed | 1 / 391 (0.26%) | 0 / 393 (0.00%) | 0 / 392 (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 |
| Vitamin b complex deficiency | | | |
| subjects affected / exposed | 1 / 391 (0.26%) | 0 / 393 (0.00%) | 0 / 392 (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 |

| Serious adverse events | Prevenar™ + Menitorix™ Group | | |
|---|---------------------------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 28 / 396 (7.07%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |

| | | | |
|---|-----------------|--|--|
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Haemangioma | | | |
| subjects affected / exposed | 1 / 396 (0.25%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 2 / 396 (0.51%) | | |
| occurrences causally related to treatment / all | 1 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Immune system disorders | | | |
| Hypersensitivity | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Reproductive system and breast disorders | | | |
| Genital labial adhesions | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Bronchitis chronic | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Apnoea | | | |
| subjects affected / exposed | 1 / 396 (0.25%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Allergic bronchitis | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Wheezing | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Injury, poisoning and procedural complications | | | |
| Fracture | | | |
| subjects affected / exposed | 1 / 396 (0.25%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Concussion | | | |
| subjects affected / exposed | 1 / 396 (0.25%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Contusion | | | |
| subjects affected / exposed | 1 / 396 (0.25%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Nervous system disorders | | | |
| Convulsion | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Febrile convulsion | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | |
|---|-----------------|--|--|
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 3 / 396 (0.76%) | | |
| occurrences causally related to treatment / all | 0 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastroesophageal reflux disease | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Dyspepsia | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Enteritis | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastritis | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hepatobiliary disorders | | | |
| Hepatosplenomegaly | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis atopic | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Urticaria | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Rash | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal and urinary disorders | | | |
| Cystitis noninfective | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Rickets | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 396 (0.25%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumonia | | | |
| subjects affected / exposed | 3 / 396 (0.76%) | | |
| occurrences causally related to treatment / all | 0 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Urinary tract infection | | | |
| subjects affected / exposed | 1 / 396 (0.25%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | | |
|---|-----------------|--|--|--|
| Gastroenteritis | | | | |
| subjects affected / exposed | 5 / 396 (1.26%) | | | |
| occurrences causally related to treatment / all | 0 / 5 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bronchopneumonia | | | | |
| subjects affected / exposed | 3 / 396 (0.76%) | | | |
| occurrences causally related to treatment / all | 0 / 3 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Viral infection | | | | |
| subjects affected / exposed | 1 / 396 (0.25%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Abscess of eyelid | | | | |
| subjects affected / exposed | 1 / 396 (0.25%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastroenteritis escherichia coli | | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastroenteritis salmonella | | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pharyngitis | | | | |
| subjects affected / exposed | 1 / 396 (0.25%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumococcal sepsis | | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pyelonephritis acute | | | | |

| | | | | |
|---|-----------------|--|--|--|
| subjects affected / exposed | 0 / 396 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Respiratory syncytial virus bronchiolitis | | | | |
| subjects affected / exposed | 1 / 396 (0.25%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastroenteritis rotavirus | | | | |
| subjects affected / exposed | 3 / 396 (0.76%) | | | |
| occurrences causally related to treatment / all | 0 / 3 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bronchospasm | | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastroenteritis norovirus | | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastroenteritis viral | | | | |
| subjects affected / exposed | 1 / 396 (0.25%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Infectious mononucleosis | | | | |
| subjects affected / exposed | 1 / 396 (0.25%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Influenza | | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Kawasaki's disease | | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Laryngitis | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Measles | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Meningitis viral | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Otitis media | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Otitis media acute | | | |
| subjects affected / exposed | 1 / 396 (0.25%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pseudocroup | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 396 (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 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 2 / 396 (0.51%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Amino acid metabolism disorder | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 396 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vitamin b complex deficiency | | | |
| subjects affected / exposed | 0 / 396 (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 | GSK 1024850A + Meningitec™ Group | GSK 1024850A + NeisVac-C™ Group | GSK 1024850A + Menitorix™ Group |
|---|----------------------------------|---------------------------------|---------------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 301 / 391 (76.98%) | 294 / 393 (74.81%) | 293 / 392 (74.74%) |
| General disorders and administration site conditions | | | |
| Pain | | | |
| alternative dictionary used: MedDRA 10.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[1] | 213 / 381 (55.91%) | 208 / 380 (54.74%) | 212 / 381 (55.64%) |
| occurrences (all) | 213 | 208 | 212 |
| Redness | | | |
| alternative dictionary used: MedDRA 10.0 | | | |

| | | | |
|--|---------------------------|---------------------------|---------------------------|
| alternative assessment type: Systematic subjects affected / exposed ^[2] occurrences (all) | 255 / 381 (66.93%) 255 | 236 / 380 (62.11%) 236 | 242 / 381 (63.52%) 242 |
| Swelling alternative dictionary used: MedDRA 10.0 alternative assessment type: Systematic subjects affected / exposed ^[3] occurrences (all) | 216 / 381 (56.69%) 216 | 189 / 380 (49.74%) 189 | 207 / 381 (54.33%) 207 |
| Drowsiness alternative dictionary used: MedDRA 10.0 alternative assessment type: Systematic subjects affected / exposed ^[4] occurrences (all) | 268 / 381 (70.34%) 268 | 276 / 380 (72.63%) 276 | 265 / 381 (69.55%) 265 |
| Fever >= 38.0°C alternative dictionary used: MedDRA 10.0 alternative assessment type: Systematic subjects affected / exposed ^[5] occurrences (all) | 247 / 381 (64.83%) 247 | 258 / 380 (67.89%) 258 | 223 / 381 (58.53%) 223 |
| Irritability alternative dictionary used: MedDRA 10.0 alternative assessment type: Systematic subjects affected / exposed ^[6] occurrences (all) | 301 / 381 (79.00%) 301 | 294 / 380 (77.37%) 294 | 293 / 381 (76.90%) 293 |
| Loss of appetite alternative dictionary used: MedDRA 10.0 alternative assessment type: Systematic subjects affected / exposed ^[7] occurrences (all) | 203 / 381 (53.28%) 203 | 200 / 380 (52.63%) 200 | 209 / 381 (54.86%) 209 |
| Infections and infestations Upper respiratory tract infection alternative dictionary used: MedDRA 10.0 subjects affected / exposed ^[8] occurrences (all) | 30 / 385 (7.79%) 30 | 30 / 387 (7.75%) 30 | 28 / 386 (7.25%) 28 |

| Non-serious adverse events | Prevenar™ + Menitorix™ Group | | |
|---|---------------------------------|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 281 / 396 (70.96%) | | |
| General disorders and administration site conditions | | | |
| Pain | | | |
| alternative dictionary used: MedDRA 10.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[1] | 185 / 386 (47.93%) | | |
| occurrences (all) | 185 | | |
| Redness | | | |
| alternative dictionary used: MedDRA 10.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[2] | 239 / 386 (61.92%) | | |
| occurrences (all) | 239 | | |
| Swelling | | | |
| alternative dictionary used: MedDRA 10.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[3] | 190 / 386 (49.22%) | | |
| occurrences (all) | 190 | | |
| Drowsiness | | | |
| alternative dictionary used: MedDRA 10.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[4] | 252 / 386 (65.28%) | | |
| occurrences (all) | 252 | | |
| Fever >= 38.0°C | | | |
| alternative dictionary used: MedDRA 10.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[5] | 218 / 386 (56.48%) | | |
| occurrences (all) | 218 | | |
| Irritability | | | |
| alternative dictionary used: MedDRA 10.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[6] | 281 / 386 (72.80%) | | |
| occurrences (all) | 281 | | |

| | | | |
|--|---------------------------|--|--|
| Loss of appetite alternative dictionary used: MedDRA 10.0 alternative assessment type: Systematic subjects affected / exposed ^[7] occurrences (all) | 196 / 386 (50.78%) 196 | | |
| Infections and infestations Upper respiratory tract infection alternative dictionary used: MedDRA 10.0 subjects affected / exposed ^[8] occurrences (all) | 32 / 390 (8.21%) 32 | | |

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Analysis for this Event was only performed on subjects for whom the specified symptom was reported.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Analysis for this Event was only performed on subjects for whom the specified symptom was reported.

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Analysis for this Event was only performed on subjects for whom the specified symptom was reported.

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Analysis for this Event was only performed on subjects for whom the specified symptom was reported.

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Analysis for this Event was only performed on subjects for whom the specified symptom was reported.

[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Analysis for this Event was only performed on subjects for whom the specified symptom was reported.

[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Analysis for this Event was only performed on subjects for whom the specified symptom was reported.

[8] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: This event only concerns subjects with at least one vaccination dose documented at the exclusion of the 24 subjects from a center located in Germany (6 in each group) were later eliminated and excluded from efficacy analyses due to protocol compliance following findings of a for cause audit.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported