

MENITORIX®

PRODUCT INFORMATION

NAME OF THE MEDICINE

Haemophilus influenzae type b Polyribose ribitol phosphate and serogroup C Meningococcal polysaccharide conjugate vaccine (Hib-MenC).

DESCRIPTION

Menitorix is supplied as a white powder of Hib-MenC vaccine in a glass vial, together with 0.5 ml of clear colourless diluent in a pre-filled syringe for a 1 dose vaccine.

After reconstitution, one dose (0.5 ml) contains:

<i>Haemophilus influenzae</i> type b Polyribose ribitol phosphate	5 µg
conjugated to tetanus toxoid as carrier protein	12.5 µg
Group C Meningococcal polysaccharide	5 µg
conjugated to tetanus toxoid as carrier protein	5 µg

The powder for reconstitution also contains the excipients, trometamol and sucrose. The diluent contains 0.9% sodium chloride in water for injections.

PHARMACOLOGY

Menitorix confers immunisation against *Haemophilus influenzae* type b and *Neisseria meningitidis* serogroup C. Conjugation of polysaccharide antigens with carrier protein is thought to result in T-cell dependant activation of polysaccharide specific B lymphocytes leading to B-cell antibody response and induction of immunological memory.

CLINICAL TRIALS

Menitorix has been studied in clinical trials in children between the ages of 6 weeks to 2 years in both primary and booster vaccination, administered concomitantly with other routine childhood vaccines. These included *Infanrix Penta* (DTPa-HBV-IPV) or *Infanrix IPV* (DTPa-IPV) in the primary vaccination studies. In booster studies, depending on study and group, Menitorix was administered alone, or with *Infanrix Penta* or a DTPa containing vaccine or with *Priorix* (MMR vaccine). In addition, pneumococcal conjugate vaccines (10-valent *Synflorix* and 7-valent) were co-administered.

The trials demonstrated non-inferiority of the immune responses elicited by Menitorix compared to the responses elicited by commercially available, comparator vaccines; *Infanrix hexa* (DTPa-HBV-IPV/Hib), DTPa-IPV-Hib and Hiberix (Hib) for investigation of the Hib response; and for investigation of the MenC response a MenC vaccine conjugated with *Corynebacterium diphtheriae* (CRM).

Immunogenicity against *Haemophilus influenzae* type b was evaluated by measuring anti-polyribosylribitol phosphate antibodies (anti-PRP) with an enzyme-linked immunosorbent assay (ELISA). Immunogenicity against *Neisseria meningitidis* serogroup C was measured by a serum bactericidal activity assay using rabbit complement (rSBA-MenC).

The correlates indicative of protection in the Menitorix development program were an anti-PRP antibody concentration of 0.15µg/mL and a rSBA-MenC antibody titre of 1:8, which are very widely accepted.

Study Hib-MenC-TT-016 was a pivotal clinical trial conducted in Australia and according to the National Immunisation Program, to evaluate the use of Menitorix as a single dose in children primed in infancy with a Hib vaccine but not with a MenC vaccine.

Primary vaccination course

The antibody responses after completion of a 3-dose primary vaccination course of Menitorix at one month after the second and third doses were as follows:

Table 1: Antibody response of Menitorix co-administered with DTPa-IPV or DTPa-HBV-IPV vaccines with or without co-administration with a pneumococcal conjugate vaccine

Antigen	Response	Antibody response of Menitorix*			
		2-3-4 month schedule		2-4-6 month schedule	
		After two doses ¹	After three doses‡	After two doses ²	After three doses
Anti-PRP	% ≥0.15µg/ml (n/N)	96.8% (90/93)	100% (335/335)	94.1% (430/457)	99.3% (450/453)
	% ≥1 µg/ml (n/N)	76.3% (71/93)	97.3% (326/335)	67.2% (307/457)	96.9% (439/453)
	GMC (µg/ml) (N)	3.4 (93)	11.2 (335)	2.1 (457)	12.4 (453)
rSBA-MenC ³	% ≥1:8 (n/N)	100% (93/93)	98.8% (326/330)	98.4% (438/445)	99.7% (367/368)
	% ≥1:32 (n/N)	98.9% (92/93)	97.9% (323/330)	97.5% (434/445)	99.7% (367/368)
	% ≥1:128 (n/N)	98.9% (92/93)	92.4% (305/330)	90.6% (403/445)	97.0% (357/368)
	GMT (N)	680 (93)	685 (330)	581 (445)	1735

N= number of subjects with available results

n/%= number/percentage of subjects with titre within pre-specified range

¹Bloodsampling one month after the second dose

²Bloodsampling two months after the second dose

³Testing performed at GSK laboratories

PRP= polyribosylribitol phosphate

rSBA-MenC= functional anti-meningococcal serogroup C activity

GMC or GMT= geometric mean antibody concentration or titre

*co-administered with DTPa-IPV, Infanrix Penta® or DTPa-HBV-IPV vaccines with or without co-administration with a pneumococcal conjugate vaccine (10-valent, Synflorix®, 7-valent pneumococcal conjugate vaccine)

‡= subjects ≤18 weeks of age at time of third Menitorix dose

Antibody persistence pre-booster

Antibody persistence after a 3 dose primary vaccination course up to pre boosting time point has been demonstrated for Menitorix in five clinical trials with subjects aged 11-18 months and primed with Menitorix in infancy at 2-3-4 or 2-4-6 months of age. Following completion of the 3 dose primary series with Menitorix, 97.0% of the

subjects (847/873) had anti-PRP titers $\geq 0.15 \mu\text{g/ml}$ and 84.9% of the subjects had rSBA-MenC* titres $\geq 1:8$ (595/701).

*Testing performed at GSK laboratories

Booster vaccination

In six clinical trials booster vaccination was given at age 12 to 15 months. The antibody responses one month after administration of a booster dose of Menitorix were as follows:

Table 2: Antibody response 1 month after administration of a booster dose of Menitorix

Antigen	Response	Primary vaccination history		
		Subjects primed with 3 doses of Menitorix ¹	Subjects primed with 2 doses of NeisVac-C ²	Subjects primed with 3 doses of MenC-CRM ₁₉₇ ²
Anti-PRP	% $\geq 0.15 \mu\text{g/ml}$ (n/N)	100% (780/780)	100% (165/165)	100% (305/305)
	% $\geq 1 \mu\text{g/ml}$ (n/N)	100% (780/780)	98.8% (163/165)	99.0% (302/305)
	GMC ($\mu\text{g/ml}$) (N)	70.1 (780)	77.2 (165)	38.2 (305)
rSBA-MenC ³	% $\geq 1:8$ (n/N)	99.5% (621/624)	99.4% (166/167)	97.7% (297/304)
	% $\geq 1:32$ (n/N)	99.4% (620/624)	99.4% (166/167)	96.4% (293/304)
	% $\geq 1:128$ (n/N)	98.2% (613/624)	99.4% (166/167)	89.1% (271/304)
	GMT (n/N)	3486 (624)	11710 (167)	575 (304)

N= number of subjects with available results

n/%=number/percentage of subjects with titre within pre-specified range

PRP= polyribosylribitol phosphate

rSBA-MenC= functional anti-meningococcal serogroup C activity

GMC or GMT= geometric mean antibody concentration or titre

¹ Co-administered with DTPa-IPV or with DTPa-HBV-IPV with or without co-administration with a pneumococcal conjugate vaccine (10-valent, Synflorix® or 7-valent pneumococcal conjugate vaccine)

²Co-administered with DTPa-Hib-TT containing vaccines

³Testing performed at GSK laboratories

Immunogenicity of a single dose in MenC-unprimed toddlers

A study was carried out in Australia in toddlers primed in infancy with a Hib conjugate vaccine but not with a Men C conjugate vaccine. These participants had received Hib vaccine either as 2 doses of a Hib-outer membrane protein [Hib-OMP] containing vaccine or as 3 doses of Hib-TT (as part of a combination vaccine with diphtheria, tetanus, acellular pertussis). This study investigated the non-inferiority of one dose of Menitorix compared with co-administration of Hib-TT and MenC-CRM vaccines. Both groups also received measles-mumps-rubella vaccine, *Priorix*®.

The data in Table 3 demonstrate non-inferiority of Menitorix to the comparator (Hib+MenC) based on the pre-specified non-inferiority in terms of percentages of subjects with rSBA-MenC titres $\geq 1:8$ and percentages of subjects with anti-PRP antibody concentrations $\geq 0.15 \mu\text{g/mL}$.

Table 3: Difference between the Menitorix group and the Hib+MenC group in terms of % of subjects with rSBA-MenC titre $\geq 1:8$ and anti-PRP concentration $\geq 0.15 \mu\text{g/mL}$, one month after the administration of the vaccine dose

Criteria	HibMenC		Hib+ MenC		Menitorix v/s Hib+MenC		
	N	%	N	%	Difference	95% CI	
rSBA-MenC antibodies						LL	UL
≥1:8	281	99.6	98	100	-0.36	-1.99*	3.43
Anti-PRP antibodies							
≥0.15 µg/mL	292	100	100	100	0.00	-1.30*	3.71

HibMenC= *Menitorix + Priorix*

Hib+ MenC= *Hiberix + MenC-CRM + Priorix*

N = number of subjects with available results

% = percentage of subjects with concentration or titres ≥ the specified cut-off

95% CI = 95% Standardized asymptotic confidence interval; LL = lower limit, UL = upper limit

*Non-inferiority criterion for the primary endpoint met (the lower limit of the 95% CI >-10 % for vaccine group differences [Menitorix minus Hib plus MenC]).

The antibody responses after the administration of a single dose of Menitorix in toddlers primed in infancy with a Hib conjugate vaccine but not with a meningococcal C conjugate vaccine was evaluated at months 1, 12, 48 and 60 after the vaccination with Menitorix (Table 4)..

Table 4: Antibody levels at Months 1, 12, 48 and 60 persistence time-points after administration of one single dose of Menitorix¹ or with Hib and MenC-CRM¹ vaccines in toddlers primed in study Hib-MenC-TT-016 (ATP cohort for persistence adapted for each time-point)

Time-point (Month)	Menitorix ¹				Hib+MenC-CRM ₁₉₇ ¹			
	1	12	48	60	1	12	48	60
Anti-PRP antibodies								
N	292	255	204	191	100	91	73	67
% ≥0.15 micrograms/ml	100	98.8	99.0	100	100	100	100	100
% ≥1 micrograms/ml	97.9	82.0	70.6	67.5	100	87.9	78.1	70.1
GMC (micrograms/ml)	46.6	3.5	2.1	2.1	74.0	4.8	3.0	2.5
rSBA-MenC ²								
% ≥1:8	94.1	40.2	12.5	19.0	98.3	34.8	12.3	25.0
% ≥1:128	79.4	10.3	3.4	6.2	75.0	17.4	5.5	10.3
GMT	257	10.0	5.3	6.6	265	13.4	6.0	8.5

N= number of subjects with available results

n/= number/percentage of subjects with titres equal to or above the cut-off

GMC or GMT= geometric mean antibody concentration or titre

¹co-administered with a MMR vaccine

² testing performed at Public Health England (PHE) in the United Kingdom. Testing for months 1 and 12 time-points were performed post-hoc on available samples

Long term persistence

Long term antibody persistence was evaluated in subjects primed and boosted with Menitorix.

A study was conducted in subject primed at 2-3-4 months of age with either Menitorix co-administered with *Infanrix-IPV* or with MenC-CRM vaccine co-administered with

DTPa-HBV-IPV vaccine. These subjects received a booster dose of Menitorix co-administered with Priorix at 12-15 months of age. Twelve months after booster vaccination, all subjects (N=261) had anti-PRP antibody concentrations $\geq 0.15 \mu\text{g/ml}$, while 89.0% (178/200) of the subjects primed with Menitorix and 69.5% (41/59) of the subjects primed with a MenC-CRM vaccine had anti-SBA MenC titers ≥ 8 .

In another study 100% of the subjects (n=52) primed with Menitorix and *Infanrix Penta* and boosted with Menitorix at respectively 2-4-6 and 13-14 months of age had anti-PRP concentrations of $\geq 0.15 \mu\text{g/ml}$ eighteen months after the administration of the Menitorix booster dose. At that time, 86.5% (45/52) of the subjects had anti-SBA-MenC titres $\geq 1:8$.

Estimates of vaccine effectiveness from the UK's routine immunisation programme (using various quantities of three meningococcal serogroup C conjugate vaccines other than Menitorix) covering the period from introduction at the end of 1999 to March 2004 have demonstrated the need for a booster dose after completion of the primary series (three doses administered at 2, 3 and 4 months). Within one year of completion of the primary series, vaccine effectiveness in the infant cohort was estimated at 93% (95% confidence intervals 67-99%). However, more than one year after completion of the primary series, there was clear evidence of waning protection.

Up to 2007, the overall estimates of effectiveness in age cohorts from 1-18 years that received a single dose of meningococcal group C conjugate vaccine during the initial catch-up vaccination programme in the UK fall between 83 and 100%.

Study Hib-MenC-TT-035 evaluated the long-term antibody persistence in children up to 6 years of age who previously received a full vaccination course (primary and booster vaccination) with Menitorix or MenC conjugate vaccines (MenC-CRM197 or MenC-TT) co-administered with DTPa-containing and pneumococcal conjugate vaccines (10- or 7-valent). The percentage of subjects with rSBA-MenC* titres $\geq 1:8$ at 6 years of age was at least 25.4% in the children that received Menitorix, 24.2% in the children that received MenC-CRM197 and 40.1% in the children that received MenC-TT as a booster in the second year of life. The percentage of subjects with anti-PRP concentrations $\geq 0.15 \mu\text{g/mL}$ at 6 years of age was 100% in children vaccinated with Menitorix.

*testing performed at Public Health England (PHE) in the United Kingdom.

INDICATIONS

Menitorix is indicated for the prevention of invasive diseases caused by *Haemophilus influenzae* type b (Hib) and *Neisseria meningitidis* serogroup C (MenC).

CONTRAINDICATIONS

Hypersensitivity to the active substances, including tetanus toxoid, or to any of the excipients.

Hypersensitivity reaction after previous administration of Menitorix.

PRECAUTIONS

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.

Vaccination should be preceded by a review of the medical history (especially with regard to previous vaccination and possible occurrence of undesirable events) and a clinical examination.

Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. It is important that procedures are in place to avoid injury from faints.

As with other vaccines, the administration of Menitorix should be postponed in subjects suffering from acute severe febrile illness. However, the presence of a minor infection, such as a cold, should not result in the deferral of vaccination.

Menitorix will only confer protection against *Haemophilus influenzae* type b and *Neisseria meningitidis* serogroup C.

As for any vaccine, Menitorix may not completely protect against the infections it is intended to prevent in every vaccinated individual.

Immunisation with this vaccine does not substitute for routine tetanus immunisation.

No data are available on the use of Menitorix in immunodeficient subjects. In individuals with impaired immune responsiveness (whether due to the use of immunosuppressive therapy, a genetic defect, human immunodeficiency virus (HIV) infection, or other causes) a protective immune response to Hib and MenC conjugate vaccines may not be obtained. Individuals with complement deficiencies and individuals with functional or anatomical asplenia may mount an immune response to Hib and MenC conjugate vaccines; however the degree of protection that would be afforded is unknown.

There are no data available on the use of Menitorix in infants who were born before 36 weeks gestation. Therefore the degree of protection that would be afforded is unknown.

The potential risk of apnoea and the need for respiratory monitoring for 48-72h should be considered when administering the primary immunisation series to very premature infants (born \leq 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.

Although symptoms of meningism such as neck pain/stiffness or photophobia have been reported following administration of other MenC conjugate vaccines, there is no evidence that MenC conjugate vaccines cause meningitis. Clinical alertness to the possibility of co-incidental meningitis should be maintained.

Since the Hib capsular polysaccharide antigen is excreted in the urine a false positive urine test for Hib infection can be observed within 1-2 weeks following vaccination. Other tests should be performed in order to confirm Hib infection during this period.

Menitorix should under no circumstances be administered intravascularly or intradermally.

The vaccine should be given with caution to individuals with thrombocytopenia or any coagulation disorder. No data are available on subcutaneous administration of Menitorix, therefore the possibility of any toxicity or reduced efficacy that might occur with this route of administration is unknown.

The need for booster doses in subjects primed with a single dose of MenC conjugate (i.e. aged 12 months or more when first immunised) has not been established.

The duration of protection in a vaccinated individual against Meningococcal serogroup C disease is unknown. However a decline over time has been observed in the percentages of individuals with at least 1:8 rSBA-MenC titres (see section "CLINICAL TRIALS").

Use in Pregnancy:

The safety of Menitorix vaccination in pregnancy has not been assessed as the vaccine is not intended for adult use.

Use in Lactation:

The effect of Menitorix in lactation has not been assessed as the vaccine is not intended for adult use.

Fertility:

There are no data on the potential of Menitorix to impair fertility.

Carcinogenicity:

The carcinogenic potential of Menitorix has not been established.

Genotoxicity

Menitorix has not been evaluated for genotoxicity.

Interactions with other medicines:

Menitorix must not be mixed with any other vaccine in the same syringe.

Separate injection sites should be used if more than one vaccine is being administered.

Menitorix can be given concomitantly with any of the following monovalent or combination vaccines: Diphtheria (D) – Tetanus (T) – acellular Pertussis (aP) – hepatitis B vaccine (HBV) – inactivated polio vaccines (IPV), Measles-Mumps-Rubella (MMR) vaccines and pneumococcal conjugate vaccines. Clinical studies demonstrated that the immune responses and the safety profiles of the co-administered vaccines were unaffected.

Care should be taken to ensure that Menitorix is not administered concurrently with another vaccine containing either *Haemophilus influenzae* b or meningococcal C vaccine.

ADVERSE EFFECTS

Clinical Trial Data

In clinical studies, Menitorix was administered as a 3 or 2-dose primary series in infants (N=2,452) or as a booster (N=2,190) dose in the second year of life. Co-administered vaccines in studies in infants included, a DTPa-HBV-IPV vaccine or a DTPa-IPV vaccine or a DTPa-HBV-IPV vaccine and pneumococcal conjugate vaccine (10-valent, Synflorix® or 7-valent). When Menitorix was administered as a booster dose, a DTPa-HBV-IPV vaccine or a MMR vaccine or a DTPa containing vaccine and pneumococcal conjugate vaccine (10-valent, Synflorix® or 7-valent) was co-administered in some studies.

In another clinical study, Menitorix was also administered as a single dose to more than 300 toddlers (between 12 and 24 months of age) who had been primed in infancy with Hib but not with MenC conjugates. A dose of MMR vaccine was administered concomitantly.

Adverse reactions occurring during these studies were mostly reported within 48 hours following vaccination. The majority of these reactions were of mild to moderate severity and resolved during the follow-up period. There was no evidence that the reactions other than injection site reactions were related to Menitorix rather than the concomitant vaccine.

Adverse reactions considered as being at least possibly related to vaccination have been categorised by frequency as follows.

Frequencies per dose are defined as follows:

Very common: $\geq 10\%$

Common: $\geq 1\%$ and $< 10\%$

Uncommon: $\geq 0.1\%$ and $< 1\%$

Rare: $\geq 0.01\%$ and $< 0.1\%$

Very rare: $< 0.01\%$

Psychiatric disorders:

very common: irritability

uncommon: crying

rare: insomnia

Nervous system disorders:

very common: drowsiness

Gastrointestinal disorders:

very common: loss of appetite

uncommon: diarrhoea, vomiting

rare: abdominal pain

Skin and subcutaneous tissue disorders:

uncommon: dermatitis atopic, rash

General disorders and administration site conditions:

very common: injection site reactions (pain, redness and swelling), fever (rectal $\geq 38^{\circ}\text{C}$)

common: injection site reactions (including induration and nodule)

uncommon: fever (rectal $> 39.5^{\circ}\text{C}$)

rare: malaise

Post Marketing Data

Blood and lymphatic system disorders: Lymphadenopathy

Nervous system disorders: Febrile seizures, hypotonia, headache, dizziness

Respiratory, thoracic and mediastinal disorders: Apnoea in very premature infants (≤ 28 weeks of gestation)

Immune system disorders: Allergic reactions (including urticaria and anaphylactoid reactions)

Other possible side effects:

The following have not been reported in association with administration of Menitorix but have occurred very rarely during routine use of licensed meningococcal group C conjugate vaccines:

Severe skin reactions, collapse or shock-like state (hypotonic-hyporesponsiveness episode), faints, seizures in patients with pre-existing seizure disorders, hypoaesthesia, paraesthesia, relapse of nephrotic syndrome, arthralgia, petechiae and/or purpura.

DOSAGE AND ADMINISTRATION

There are no data on immunogenicity, safety and reactogenicity of Menitorix administered to pre-term infants born before 36 weeks gestation, nor in children beyond the second year of life.

Menitorix is for intramuscular injection only, preferably in the anterolateral thigh region. In children 12 to 24 months of age, the vaccine may be administered in the deltoid region (see **Precautions and Interactions**). Menitorix should not under any circumstances be administered intravascularly or intradermally.

Primary vaccination in infants from 6 weeks up to 12 months of age:

Three doses, each of 0.5 ml, should be given with an interval of at least 1 month between doses.

Booster vaccination of children primed in infancy with Hib and MenC conjugate vaccines:

A single (0.5 ml) dose of Menitorix may be used to boost immunity to Hib and MenC in children who have previously completed a primary immunisation series with Menitorix or with other Hib or MenC conjugate vaccines. The timing of the booster dose of Menitorix should be in accordance with available official recommendations and would usually be given from the age of 12 months onwards and at least 6 months after the last priming dose. The need for booster doses in subjects primed with a single dose of MenC conjugate (i.e. aged 12 months or more when first immunised) has not been established.

Vaccination of children primed in infancy with Hib but not with MenC conjugate vaccines:

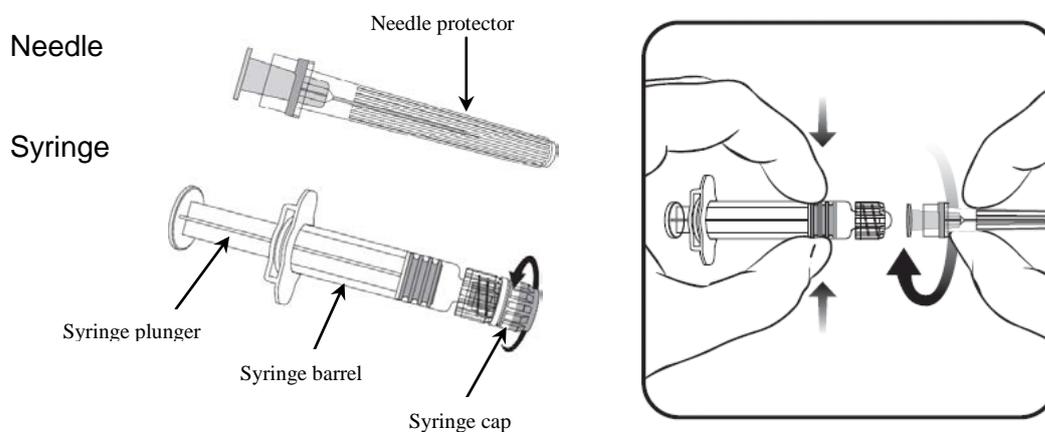
A single (0.5 ml) dose of Menitorix may be used to elicit immunity against MenC and to boost immunity to Hib. The timing of the dose should be in accordance with available official recommendations and should usually be from the age of 12 months onwards and before the age of 2 years.

Further guidance regarding the use of vaccines can be found in the Australian Immunisation Handbook (see CLINICAL TRIALS section for schedules evaluated in clinical trials).

Directions for Reconstitution

Menitorix must be reconstituted by adding the entire contents of the pre-filled syringe of diluent to the vial containing the powder.

To attach the needle to the syringe, refer to the below drawing. However, the syringe provided with Menitorix might be slightly different than the syringe described in the drawing.



1. Holding the syringe barrel in one hand (avoid holding the syringe plunger), unscrew the syringe cap by twisting it anticlockwise.
2. To attach the needle to the syringe, twist the needle clockwise into the syringe until you feel it lock (see picture).
3. Remove the needle protector, which on occasion can be a little stiff.

Add the diluent to the powder. After the addition of the diluent to the powder, the mixture should be well shaken until the powder is completely dissolved in the diluent. The reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspect prior to administration. In the event of either being observed, discard the vaccine.

A new needle should be used to administer the vaccine.

Inject the entire contents of the vial.

After reconstitution, the vaccine should be administered promptly or kept in the refrigerator (2°C – 8°C). If it is not used within 24 hours, it should be discarded.

Menitorix is for single use in a single patient only. Any unused product or waste material should be disposed of in accordance with local requirements.

OVERDOSAGE

Insufficient data are available.

Contact the Poisons Information Centre (telephone 13 11 26) for advice on overdose management.

PRESENTATION AND STORAGE CONDITIONS

Powder in a vial (type I glass) with a stopper (butyl rubber), 0.5 ml of diluent in a pre-filled syringe (type I glass) with a plunger stopper (butyl rubber) with or without separate needles in the following pack sizes:

- pack size of 1 vial of powder plus 1 pre-filled syringe of diluent with or without separate needles
- pack size of 10 vials of powder plus 10 pre-filled syringes of diluent with or without separate needles

Not all pack sizes may be marketed.

Store at 2°C – 8°C (in a refrigerator). Do not freeze.

To reduce microbiological hazard, use as soon as practicable after reconstitution. If storage is necessary, hold at 2°C – 8°C for not more than 24 hours.

Store in the original packaging in order to protect from light.

NAME AND ADDRESS OF THE SPONSOR

GlaxoSmithKline Australia Pty Ltd
Level 4, 436 Johnston Street,
Abbotsford, Victoria, 3067

POISON SCHEDULE OF THE MEDICINE

Schedule 4 – Prescription Only Medicine

Date of first inclusion in the Australian Register of Therapeutic Goods (the ARTG): 2 August 2010

Date of most recent amendment: 7 June 2016

Menitorix, Hiberix, Infanrix IPV, Infanrix Penta, Infanrix hexa, Priorix, Synflorix are registered trade marks of the GSK group of companies

Version 6.0