Pages 1-3 inclusive exempt in full under section 22(1) of the FOI Act (irrelevant information)

Product Information

Prevenar®

NAME OF VACCINE

Pneumococcal conjugate vaccine, 7-valent.

DESCRIPTION

Prevenar is a sterile, ready to use suspension for intramuscular injection. It contains saccharides of the capsular antigen of *Streptococcus pneumoniae* (pneumococcus) serotypes 4, 6B, 9V, 14, 18C, 19F and 23F individually conjugated to diphtheria CRM_{197} protein. CRM_{197} is a nontoxic variant of diphtheria toxin isolated from cultures of *Corynebacterium diphtheriae* strain C7 (β 197) and/or *Corynebacterium diphtheriae* strain C7 (β 197) pPx 350.

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

Active ingredients

Each 0.5 mL dose contains 2 micrograms of saccharide for serotypes 4, 9V, 14, 18C, 19F, and 23F, and 4 micrograms of serotype 6B per dose (16 micrograms total saccharide) conjugated to CRM_{197} carrier protein and adsorbed on aluminium phosphate (0.5 mg).

Excipients

Aluminium phosphate

Sodium chloride

Water for injections

PHARMACOLOGY

Streptococcus pneumoniae is an important cause of morbidity and mortality in persons of all ages worldwide. It is a leading cause of death and illness in infants, among the elderly, and in persons who have certain underlying medical conditions. The organism causes invasive infections, including bacteraemia and meningitis, pneumonia and other lower respiratory tract infections, and upper respiratory tract infections including otitis media and sinusitis.

Surveys[1, 2] have shown that the 7 serotypes included in the vaccine (4, 6B, 9V, 14, 18C, 19F, 23F) are likely to cover about 67% of invasive isolates in Indigenous Australian children and 80% - 85% of invasive isolates in urban Australian children.

In New Zealand, 2002 survey data[3] showed that the 7 serotypes in Prevenar would have covered 91% of invasive isolates found in children under the age of 2 years and 80% of invasive isolates found in children aged 2 to 5 years.

reduction (95% CI = 3 - 15). In Northern California, there was also a 20 % (95% CI = 2 - 35) reduction in the placement of ear tubes in vaccine recipients.

In the Finnish trial, the impact of the vaccine on total number of episodes of otitis media regardless of etiology was a statistically non-significant 6 % reduction (95% CI = -4 - 16) while in the Northern California trial the impact of the vaccine was a statistically significant 7 % reduction (95% CI = 4 - 10).

Immunogenicity

Vaccine induced antibody to capsular polysaccharide specific of each serotype are considered protective against invasive disease. The minimum protective antibody concentration against invasive disease has not been determined for any serotype.

A significant antibody response was seen following three and four doses to all vaccine serotypes in infants that received Prevenar, although geometric mean concentrations varied among serotypes. For all serotypes, peak primary series responses were seen after 3 doses, with boosting following the 4th dose. Prevenar induces functional antibodies to all vaccine serotypes, as measured by opsonophagocytosis following the primary series.

A plain polysaccharide challenge at 13 months, following the primary series with Prevenar, elicited an anamnestic (memory) antibody response for the 7 serotypes included in the vaccine which is indicative for priming.

TABLE 2
Geometric Mean Concentrations (μg/mL) of Pneumococcal Antibodies Following the Third and Fourth Doses of Prevenar® or Control* When Administered Concurrently With DTP-HbOC in the Kaiser Efficacy Study and the Finnish Otitis Media Study

Serotype	Efficacy Study				Finnish Otitis Media Study			
	Post dose 3 GMC (95% CI for Prevenar®)		Post dose 4 GMC (95% CI for Prevenar®)		Post dose 3 GMC (95% CI for Prevenar®)		Post dose 4 GMC (95% CI for Prevenar®)	
	Prevenar® †	Control*	Prevenar® †	Control*	Prevenar®†	Control*	Prevenar®†	Control*
	N=88	N=92	N=68	N=61	N=54	N=52	N=55	N=54
4	1.46 (1.19, 1.78)	0.03	2.38 (1.88, 3.03)	0.04	1.70 (1.32, 2.20)	0.05	2.56 (2.00, 3.28)	0.11
6B	4.70 (3.59, 6.14)	0.08	14.45 (11.17, 18.69)	0.17	2.00 (1.35, 2.96)	0.09	9.05 (6.50, 12.59)	0.16
9V	1.99 (1.64, 2.42)	0.05	3.51 (2.75, 4.48)	0.06	2.48 (1.97, 3.11)	0.10	3.97 (3.20, 4.91)	0.21
14	4.60 (3.70, 5.74)	0.05	6.52 (5.18, 8.21)	0.06	6.28 (4.78, 8.23)	0.21	10.82 (8.30, 14.09)	0.21
18C	2.16 (1.73, 2.69)	0.04	3.43 (2.70, 4.37)	0.07	3.55 (2.80, 4.49)	0.08	6.51 (5.04, 8.41)	0.10
19F	1.39 (1.16, 1.68)	0.09	2.07 (1.66, 2.57)	0.18	3.28 (2.57, 4.18)	0.22	4.96 (3.86, 6.37)	0.41
23F	1.85 (1.46, 2.34)	0.05	3.82 (2.85, 5.11)	0.09	2.51 (1.84, 3.43)	0.10	6.25 (4.54, 8.61)	0.15

* Control was investigational meningococcal group C conjugate vaccine (MnCC) in the Kaiser Efficacy Study and Hepatitis B vaccine in the Finnish Otitis Media Study.

† $p<0.001$ when Prevenar® compared to control for each serotype using a Wilcoxon's test in the Kaiser Efficacy Study. P-values were not calculated in the Finnish Otitis Media Study.

disease (e.g. children with congenital and acquired splenic dysfunction, HIV-infected, malignancy, nephrotic syndrome). Vaccination in high-risk groups should be considered on an individual basis.

- For children from 2 years through 5 years of age, a single dose immunisation schedule was used. Only limited data are available. A higher rate of local reactions, particularly tenderness, has been observed in children older than 24 months of age compared with infants (see ADVERSE REACTIONS).
- Prophylactic antipyretic medication is recommended:

  For all children receiving Prevenar simultaneously with vaccines containing whole cell pertussis because of a higher rate of febrile reactions (see ADVERSE REACTIONS).

  For children with seizure disorders or with a prior history of febrile seizures.

  Antipyretic treatment should be initiated whenever warranted or when the temperature rises above 39 °C.
- Prevenar is not recommended for use in adult populations.
- The use of Prevenar does not replace the use of 23-valent pneumococcal polysaccharide vaccine in children, 24 months of age or older, with conditions such as sickle cell disease, asplenia, HIV infection, chronic illness, or who are immunocompromised, and, therefore, at higher risk for invasive disease due to *S. pneumoniae*. Consideration may be given to vaccinating these children with a priming dose of Prevenar, followed by a booster dose of the 23-valent pneumococcal polysaccharide vaccine. Based on limited data, the interval between vaccination with Prevenar and vaccination with 23-valent pneumococcal polysaccharide vaccine should not be less than 8 weeks.
- Do not administer Prevenar intravenously.

Carcinogenicity, mutagenicity, impairment of fertility

Prevenar has not been evaluated for carcinogenicity, mutagenicity, or impairment of fertility.

Use in Pregnancy

Category B2

Prevenar is not indicated or recommended for use in pregnant women and has not been evaluated for potential harmful effects during pregnancy in animals or humans.

Use in Lactation

Prevenar is not recommended for use in adults. Safety during lactation has not been established. It is not known whether vaccine antigens or antibodies are excreted in human milk.

Use in Children

Prevenar has been shown to be usually well tolerated and immunogenic in infants from 6 weeks and in children up to 9 years.

The safety and effectiveness of Prevenar in children below the age of six weeks or on, or after, the 10th birthday have not been established.

If the vaccine is used in subjects deficient in producing antibody, whether due to genetic defect or immunosuppressive therapy, the expected immune response may not be achieved. However,

vaccine. In addition, in most of the reports, existing medical conditions such as history of apnoea, infection, prematurity and/or seizure were present.

Body System	**Very common (≥ 10 %):**	**Common (≥ 1 % &< 10%)**	**Uncommon (≥ 0.1% & <1 %)**	**Rare (≥ 0.01% &< 0.1%)**	**Very Rare (<0.01%)**
Administration site conditions:	Erythema, induration/ swelling, pain/tenderness.	Induration/ swelling or erythema >2.4cm. Tenderness interfering with movement.	-	-	Injection Site dermatitis, injection site urticaria, injection site pruritus.
General disorders:	Fever ≥ 38 °C.	Fever > 39 °C.	-	-	-
Gastrointestinal disorders:	Decreased appetite, vomiting, diarrhoea.	-	-	-	-
Nervous system disorders:	Drowsiness, restless sleep.	-	-	Seizures (including febrile seizures), hypotonic-hyporesponsive episode.	-
Psychiatric disorders:	Irritability.	-	-	-	-
Skin & subcutaneous tissue disorders:	-	-	Rash, urticaria or urticaria-like rash.	-	Angioneurotic oedema, erythema multiforme.
Immune System Disorders:	-	-	-	-	Hypersensitivity reaction including face oedema, dyspnoea, bronchospasm, anaphylactic/ anaphylactoid reaction including shock.
Blood and lymphatic system disorders:	-	-	-	-	Lymphadeno-pathy localised to the region of the injection site.

DOSAGE AND ADMINISTRATION

For intramuscular use only. Do not administer Prevenar intravenously, subcutaneously or intradermally, since the safety and immunogenicity of these routes have not been evaluated.

Prevenar is not to be mixed with other vaccines or products in the same syringe.

Before use, shake well to obtain a homogenous white suspension. The vaccine must not be used if it cannot be uniformly suspended. Parenteral products should be inspected visually for particulate matter or discolouration prior to use.

PRESENTATION

Prevenar is presented as a suspension in 0.5 mL single-dose glass vials and 0.5 mL pre-filled syringes in packs of 1 and 10.

STORAGE

Store at 2° to 8°C (Refrigerate. Do not freeze).

Store in original package.

NAME AND ADDRESS OF SPONSOR

Wyeth Australia Pty Limited, ABN 16 000 296 211
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☎(02) 8850 8200 or (02) 9761 8200

TGA Approval Date: 2 March 2005

Supplied in New Zealand by:

Wyeth (N.Z.) Limited
15B Vestey Drive, Mt Wellington, Auckland 1006
NEW ZEALAND
☎ (09) 573 3551

® Registered Trade Mark

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[1] Torzillo P. & Gratten M., MJA Vol 173, 2 October 2000, S52
[2] McIntyre P. & Nolan T., MJA Vol 173, 2 October 2000, S55
[3] Data provided by the Institute of Environmental Science and Research Ltd.