



29th March 2010

TGA approval of Prevenar 13[®] (pneumococcal polysaccharide conjugate vaccine, 13-valent adsorbed) for use in Australia

Wyeth is pleased to announce that Prevenar 13 has been approved by the TGA.

Prevenar 13 is indicated for "Active immunisation for the prevention of disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F (including invasive disease, pneumonia and acute otitis media) in infants and children from 6 weeks up to 5 years of age."¹

Based on surveillance performed before the introduction of Prevenar (pneumococcal conjugate vaccine, 7-valent), Prevenar 13 is expected to cover 93.3% of the serotypes causing invasive pneumococcal disease in Australia, in children under 5 years of age¹. Prevenar 13 has the broadest coverage of any pneumococcal conjugate vaccine and is the only pneumococcal conjugate vaccine which provides direct protection for serotypes 3, 6A and 19A¹⁻³. Built on the scientific foundation of Prevenar, Prevenar 13 uses the same established single-protein carrier, CRM₁₉₇¹.

One month after the three-dose primary series, Prevenar 13 elicits a significant antibody response for all 13 serotypes¹. Prevenar 13 also elicits significant functional antibodies for all 13 serotypes and is expected to provide significant protection against pneumococcal disease caused by these serotypes¹.

Transition is easy - Infants and children who have begun immunisation with Prevenar may complete immunisation by switching to Prevenar 13 at any point in the schedule¹.

Wyeth has made a submission to the PBAC for inclusion of Prevenar 13 on the NIP. We will update you on the progress and outcome of that submission in the future.

Please contact me if you have any questions regarding Prevenar 13.

Kind regards

A handwritten signature in black ink that reads "Lauren Conyer".

Lauren Conyer
Head of Vaccines

Phone: +61 2 9813 4261

**PBS Information: This product is not listed on the National
Immunisation Program (NIP) or the PBS**

Prevenar 13[®] suspension for I.M. injection

Please review full Product Information before prescribing, available on request ☎
1800 675 229.

Indications: Active immunisation for the prevention of disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F (including invasive disease, pneumonia and acute otitis media) in infants and children from 6 weeks up to 5 years of age. **Dose:** 0.5 mL I.M. Do not administer to the gluteal region or intravascularly (see also Precautions). **Infants:** 6 weeks of age: 3 doses at least one month apart. A single booster should be given in the second year, at least 2 months after the primary series. *Previously unvaccinated infants 7 to 11 months of age:* 2 doses approx. 1 month apart, followed by a third dose in their second year, at least 2 months after the second dose. *Previously unvaccinated children 12 to 23 months of age:* 2 doses at least 2 months apart. Previously unvaccinated children 24 months of age or older should receive a single dose. **Contraindications:** Hypersensitivity to any component of the vaccine, including diphtheria toxoid. Allergic reaction or anaphylactic reaction following prior administration of Prevenar. **Precautions:** Do not administer intravenously, intravascularly, intradermally or subcutaneously. Avoid injecting into or near nerves or blood vessels. Do not inject into gluteal area. Postpone administration in subjects suffering from acute moderate or severe febrile illness. Prevenar 13 will not protect against *Streptococcus pneumoniae* serotypes other than those included in the vaccine nor other micro-organisms that cause invasive disease, pneumonia, or otitis media. Prevenar 13 may not protect all individuals receiving the vaccine from pneumococcal disease. Infants or children with thrombocytopenia or any coagulation disorder. Appropriate treatment must be available in case of a rare anaphylactic event following administration. Safety and immunogenicity data in children with sickle cell disease and other high-risk groups for invasive pneumococcal disease are not yet available for Prevenar 13. Prophylactic antipyretic medication recommended for children receiving Prevenar 13 simultaneously with whole-cell pertussis vaccines, or children with seizure disorders or prior history of febrile seizures. Antipyretic treatment should be initiated whenever warranted as per local treatment guidelines. The potential risk of apnoea should be considered when administering the primary immunisation series to very premature infants. **Adverse Effects:** *Very common:* Injection site erythema, induration/swelling, pain/tenderness, fever, decreased appetite, drowsiness, restless sleep, irritability. *Common:* Vomiting, diarrhoea, rash. *Uncommon:* Urticaria or urticaria-like rash, seizures, crying. *Rare:* Hypersensitivity reaction including face oedema, dyspnoea, bronchospasm. Based on Product Information: Prevenar 13-PI-Aus-16Mar10A.24.03.10 W20100066

References

¹ Prevenar 13[®] Approved Product Information

² Prevenar[®] Approved Product Information

³ Synflorix[®] Approved Product Information (Synflorix is a registered trademark of GSK)