

Newborn Use Only

Alert	Increased risk of fever when pneumococcal conjugate vaccine concurrently administered with other vaccines. Register the vaccination with the National Immunisation Registry by faxing a copy of the immunisation details from “My personal health record” to Anne Allen on 93824309.
Indication	1. Primary immunisation against pneumococcal disease in infants at 6 weeks/2 months, 4 and 6 months of age. 2. Booster dose at 12 months in at risk children: <ul style="list-style-type: none"> • Indigenous children in Northern Territory, Queensland, South Australia or Western Australia. • Children with a medical condition associated with an increased risk of invasive pneumococcal disease. • Preterm infants < 28 weeks gestation 3. Catch-up vaccination schedules in children up to 5 years of age.
Action	Induces the production of antibodies against <i>Streptococcus pneumoniae</i> .
Drug Type	Vaccine Conjugated pneumococcal vaccine composed of pneumococcal serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F each conjugated to CRM197 carrier protein.
Trade Name	Prevenar 13.
Presentation	Suspension in pre-filled syringe.
Dosage/Interval	0.5 mL.
Route	IM
Preparation/Dilution	
Administration	1. May administer oral sucrose 2 minutes prior to injection (observe local pain policy). 2. Shake syringe vigorously immediately prior to use to obtain an homogenous, white suspension. 3. Administer 0.5 ml of suspension by intramuscular injection (IMI) to the anterolateral aspect of the thigh (slowly to reduce pain). 4. Administer on the opposite limb from other concurrently administered vaccines (e.g. INFANRIX hexa).
Monitoring	1. Observe for 15 minutes after vaccination for any Adverse Event Following Immunisation (AEFI). 2. Pain: Refer to local pain relief policy. 3. Body temperature. 4. Infants with a history of febrile convulsions should be closely followed up as such adverse events may occur within 2 to 3 days post-vaccination.
Contraindications	<ul style="list-style-type: none"> • Anaphylaxis following a previous dose of pneumococcal vaccine. • Hypersensitivity to any vaccine component.
Precautions	<ul style="list-style-type: none"> • Significant acute illness or temperature greater than 38.5°C – postpone vaccine until neonatologist approves. • Immunosuppressed patients
Drug Interactions	N/A
Adverse Reactions	Common (1–10%): Pain, inflammation, redness, swelling, injection site mass persisting for up to a few days. Uncommon (0.1–< 1%): Headache, fever, lethargy, malaise, myalgia, irritability, restlessness, diarrhoea, vomiting. Any serious or unexpected adverse event following immunisation should be promptly reported. Providers should use clinical judgment in deciding which adverse events to report and parents/carers should be encouraged to notify the immunisation service provider or health authorities of any untoward medical occurrence that follows immunisation. Each State/Territory has its own contact details for notification. Contact telephone number for NSW Public Health Unit is 1300 066 055.
Compatibility	NA
Incompatibility	Do not mix with any other vaccines in the same syringe.
Stability	Should be injected promptly. However, the vaccine stable for up to eight hours at room temperature.

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Storage	Store between 2 and 8°C. Do NOT freeze.
Special Comments	<ol style="list-style-type: none"> 1. There are two different kinds of pneumococcal vaccines — pneumococcal conjugate vaccines (PCVs) and pneumococcal polysaccharide vaccine (PPVs). PCVs are vaccines based on chemical coupling of <i>S. pneumoniae</i> to an immunogenic protein carrier, which enhances antibody response and induces immune memory in young infants as opposed to PPVs which are associated with poor immunogenicity in children < 2 years. 2. PCV vaccines vary in the number of pneumococcal serotypes included and the proteins used for conjugation. 3. Prevenar 13 is the 13vPCV that has been registered in Australia since 2010 and used in the National Immunisation Program since July 2011. 4. Completion of a primary course of PCV with the same formulation is generally preferred — however if vaccination has commenced with a 10vPCV (e.g. overseas), completion of the course with a 13vPCV is acceptable. Refer to The Australian Immunisation Handbook.
Evidence summary	<p>Immunisation schedule</p> <p>The WHO, the Australian Government and the New South Wales Immunisation schedule recommend the inclusion of PCVs in childhood immunisation programmes.^{1,3,6}</p> <p>When primary immunisation is initiated with one of the PCV vaccines it is recommended that the schedule be completed with the same product. However, if this is not possible, the another PCV product should be used.³</p> <p>The WHO recommends 3 primary doses (3p+0 schedule) with the 2 primary doses plus a booster (2p+1) as an alternative schedule.^{3,5}</p> <p>Efficacy and safety</p> <p>Currently available PCVs are safe and efficacious and the increased number of serotypes represents significant progress in the fight against pneumococcal morbidity. There are considered safe in all target groups for vaccinations; however, there is no information on the safety of PCVs during pregnancy.³</p> <p>The 10vPCV and 13vPCV vaccines have comparable safety and efficacy profiles. The choice of PCV is dependent on the locally prevalent serotypes and vaccine supply.³</p> <p>The 13vPCV has been demonstrated to be safe and immunogenic in both children and adults. It has high global serotype coverage (> 70%) and increased coverage of serotypes causing invasive pneumococcal disease (IPD).⁴</p> <p>The differences in clinical outcomes between 3p+0 and 2p+1 may be minimal in the presence of herd protection. Giving 3 primary doses (3p+0 schedule) may be preferred in settings in which disease rates peak before the end of the first year of life and the 2p+1 schedule may be preferred in settings in which duration of protection may be a concern, especially for ongoing protection against serotype 1.^{3,5}</p>
References	<ol style="list-style-type: none"> 1. Australian Government Department of Health. The Australian Immunisation Handbook, 10th Edition 2013 (Updated June 2015) 2. MIMS online available via CIAP. Accessed 9/3/16 3. World Health Organisation. Pneumococcal vaccines - WHO position paper. Wkly Epidemiol Rec 2012; 87 (14): 129-144. (http://www.who.int/wer/2012/wer8714/en/) 4. Jefferies JMC, Macdonald E, Faust SN and Clarke SC. 13-valent-pneumococcal vaccine (PCV13). Human Vaccines 2011; 7 (10): 1012-18. 5. Whitney CG, Goldblatt D and O'Brien KL. Dosing schedules for pneumococcal conjugate vaccine – Considerations for policy makers. Pediatr Infect Dis J 2014; 33 (1): 172-181. 6. New South Wales Immunisation schedule April 2016.

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