Pneumococcal vaccine – Prevenar 13

Newborn use only

2021

Alert	Increased risk of fever when concurrently administered with other vaccines.
Indication	1. Primary immunisation against pneumococcal disease in all infants at 6 weeks/2 months, 4 and 12 months of age. (1,2) 2. Additional dose at **6 months** of age is recommended for: Preterm Infants born less than 28 weeks gestation Aboriginal and Torres Strait Islander children living in Northern Territory, Queensland, South Australia and Western Australia. Infants with risk conditions for pneumococcal disease (Refer to Australian Immunisation Handbook for full list) 3. Catch-up vaccination schedules in children up to 5 years of age.
Action	Induces the production of antibodies against *Streptococcus pneumoniae*.
Drug type	13-valent pneumococcal conjugate vaccine (13vPCV) containing pneumococcal capsular polysaccharides of serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F.
Trade name	Prevenar 13
Presentation	Suspension in pre-filled syringe
Dose	0.5 mL
Dose adjustment	Not applicable
Maximum dose	Not applicable
Total cumulative dose	Not applicable
Route	IM
Preparation	Pre-filled syringe, ready to administer
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 a 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	• Anaphylaxis following a previous dose of pneumococcal vaccine. • Anaphylactic hypersensitivity to any vaccine component.
Precautions	Children can receive 13vPCV and inactivated influenza vaccine at the same visit if both vaccines are due. There is a slightly higher risk of fever and febrile convulsions in children aged 6 months to <5 years (especially those aged 12–24 months) when they received 13vPCV and inactivated influenza vaccine at the same time. • Significant acute illness or temperature greater than 38.5°C – postpone vaccine until neonatologist approves • Immunosuppressed patients
Drug interactions	Co-administration of 13vPCV with Menactra (quadrivalent MenACWY vaccine) should be avoided. This is because Menactra may interfere with the immune response against some pneumococcal serotypes. Two other brands of MenACWY vaccine, Menveo or Nimenrix, are available and can be co-administered with 13vPCV without such interference. If 13vPCV and Menactra are inadvertently co-administered, a repeat dose of either vaccine is not needed.
Adverse reactions	About 50% had any pain/tenderness and erythema at the injection site. About 33% had any hardness (induration) or swelling. About 8% had pain interfering with movement. About 13% had moderate erythema and induration: more common at 12 months of age. About 37% reported fever, and about 5% had fever >39°C. More common at 12 months of age. About 70% had irritability. About 60% had drowsiness/increased sleep. About 39% had decreased appetite. 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	Not applicable.
Incompatibility	Do not mix with any other vaccines in the same syringe.
Stability	Should be injected promptly. However, the vaccine is stable for up to eight hours at room temperature.
Storage	Store between 2 and 8°C. Do NOT freeze.
Excipients	Aluminium phosphate, sodium chloride, succinic acid, polysorbate 80
Special comments	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 *S. pneumoniae* 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	**Efficacy** The vaccine effectiveness of 3 doses of 13vPCV against IPD due to 13vPCV serotypes was estimated at 86% for non-Indigenous children in Australia. These data were similar to those from a previous case–control study, which showed vaccine effectiveness of 87% for 3 doses of 13vPCV.(1) The efficacy of 13vPCV against vaccine-type invasive pulmonary disease was 77.3%, and 40.3% against vaccine-type community acquired pneumonia in people with risk conditions including heart disease, lung disease, asthma, diabetes, liver disease, smoking and splenectomy. Although these point estimates were lower than for healthy study participants, the confidence intervals overlapped, indicating a statistically similar response to the vaccine. Vaccine efficacy is expected to be the same or better in younger adults with these risk conditions. (1)
Practice points	
References	1. Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook, Australian Government Department of Health, Canberra, 2018, immunisationhandbook.health.gov.au. 2. New South Wales Immunisation schedule July 2020. https://www.health.nsw.gov.au/immunisation/publications/nsw-immunisation-schedule.pdf

VERSION/NUMBER	**DATE**
Original 1.0	**15/11/2016**
Version 2.0	**4/05/2021**
REVIEW	4/05/2026

Authors Contribution

Original author/s	Ahmed Khan
Current version author/s	Eszter Jozsa, Srinivas Bolisetty
Evidence Review	
Expert review	
Nursing Review	Eszter Jozsa, Kirsty Minter
Pharmacy Review	Cindy Chen
ANMF Group contributors	Rajesh Maheshwari, Nilkant Phad, Bhavesh Mehta, John Sinn, Michelle Jenkins, Jessica Mehegan, Helen Huynh, Simarjit Kaur, Sarah Woodland
Final editing and review of the original	Ian Whyte
Electronic version	Cindy Chen, Ian Callander
Facilitator	Dr Srinivas Bolisetty