Pneumococcal vaccine – Prevenar 20

Newborn use only

2025

<table>
<tr><td>Alert</td><td>Infants who previously received 1 or 2 doses of Prevenar 13 should transition to Prevenar 20 at their next schedule point to complete the vaccination schedule.
Prevenar 20 can be safely administered concomitantly with other monovalent or combination vaccines including influenza, rotavirus and RSV specific monoclonal antibody.</td></tr>
<tr><td>Indication</td><td>1. Primary immunisation against pneumococcal diseases such as pneumonia, bacteraemia, meningitis and otitis media in children aged 6 weeks or older.[1-3]
2. Catch-up vaccination in children aged 7 months to 5 years.[4,5]</td></tr>
<tr><td>Action</td><td>Modifies the immune response leading to enhanced antibody production and generation of memory B-cells, allowing for an anamnestic response on re-exposure to the serotypes contained within the vaccine.</td></tr>
<tr><td>Drug type</td><td>20-valent pneumococcal conjugate vaccine (20vPCV) containing pneumococcal purified capsular polysaccharide serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F.[1-3]</td></tr>
<tr><td>Trade name</td><td>Prevenar 20</td></tr>
<tr><td>Presentation</td><td>Suspension in 0.5 ml pre-filled syringe</td></tr>
<tr><td>Dose</td><td>0.5 ml

Primary vaccination Schedule[4]
<table>
<tr><th></th><th>First dose</th><th>Subsequent doses</th><th>Booster</th></tr>
<tr><td>Born at or after 28 weeks gestation</td><td>6 to 8 weeks</td><td>4 months</td><td>12 months</td></tr>
<tr><td>Born at less than 28 weeks gestation</td><td>6 to 8 weeks</td><td>4 and 6 months</td><td>12 months</td></tr>
<tr><td>Aboriginal and Torres Strait Islander infants</td><td>6 to 8 weeks</td><td>4 and 6 months</td><td>12 months</td></tr>
<tr><td>Infants aged <12 months with risk conditions*</td><td>6 to 8 weeks</td><td>4 and 6 months</td><td>12 months</td></tr>
</table>
*The full list of risk conditions for pneumococcal disease in infants is provided in the Australian Immunisation Handbook (AIH).[3] The AIH also provides recommendations for pneumococcal vaccination for children and adolescents aged ≥12 months to <18 years with a risk condition.

Catch up vaccination
For children aged >12 months who have not completed a full course of pneumococcal conjugate vaccines, the timing and number of doses for catch-up vaccination depends on their age and previous vaccination status. Situation specific catch-up pneumococcal vaccination schedule is provided in the Australian Immunisation Handbook.[3]</td></tr>
<tr><td>Dose adjustment</td><td>Not applicable</td></tr>
<tr><td>Maximum dose</td><td>Not applicable</td></tr>
<tr><td>Route</td><td>IM</td></tr>
<tr><td>Preparation</td><td>Pre-filled syringe, ready to administer</td></tr>
<tr><td>Administration</td><td>1. May administer oral sucrose 2 minutes prior to injection (observe local pain policy).
2. Administer vaccine as soon as possible after removing from the refrigerator.
3. Shake syringe vigorously immediately prior to use to obtain a homogenous white suspension.
4. Administer 0.5 mL of suspension by intramuscular injection (IMI) to the anterolateral aspect of the thigh (slowly to reduce pain).
5. Administer preferably in opposite limb from other concurrently administered vaccines unless giving more than 2 vaccines at one visit.
Infants can receive PCV at the same time as other vaccines or immunisation products in the infant schedule, including inactivated influenza vaccine and RSV-specific monoclonal antibody.[3]</td></tr>
<tr><td>Monitoring</td><td>1. Observe for 15 minutes after vaccination for any adverse event following immunisation.
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.</td></tr>
<tr><td>Contraindications</td><td>Severe allergic reaction to pneumococcal or diphtheria vaccines or to any vaccine component.</td></tr>
<tr><td>Precautions</td><td>Thrombocytopenia, bleeding disorder, anti-malignancy treatment or other immunocompromised status.[1,2]</td></tr>
</table>

	Vaccination should be postponed in individuals suffering from acute severe febrile illness but not minor infection such as cold.[1-3] Whilst one USA study reported a higher incidence of fever and febrile convulsion when Prevenar 13 was co-administered with inactivated influenza vaccine, another study did not show the same association. Coadministration studies in children for 20vPCV and inactivated influenza vaccine are not currently available. However, 20vPCV clinical trials did not show a difference between 13vPCV and 20vPCV for febrile convulsions.[1-5]
Drug interactions	Less immunogenic in people who are immunocompromised secondary to immunosuppressive therapy. Extra doses may be needed as suggested in the immunisation handbook.[3]
Adverse reactions	**Very common** Fever, irritability, reduced appetite, drowsiness, vaccine site redness (up to 7cm), induration and tenderness. **Common** Rash, diarrhoea, vomiting, high fever (> 39^0C), limitation of limb movement due to pain. **Uncommon** Urticarial rash, vaccine site redness (more t7cm), induration and tenderness. **Rare** Vaccine site hypersensitivity 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 used immediately once removed from the refrigerator. Stable for 96 hours when stored at temperatures from 8°C to 25°C.
Storage	Store between 2 and 8°C. Pre-filled syringes should be stored in the refrigerator horizontally. Do NOT freeze.
Excipients	Aluminium phosphate, sodium chloride, succinic acid, polysorbate 80, water for injections
Special comments	1. 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. 2. PCV vaccines vary in the number of pneumococcal serotypes included and the proteins used for conjugation. 3. Prevenar 20 is funded in the Australian National Immunisation Program since September 2025. 4. Infants who previously received 1 or 2 doses of Prevenar 13 should transition to Prevenar 20 at any point in the schedule to complete the vaccination schedule.[3]
Evidence	**Efficacy** There is no efficacy data for 20vPCV. This vaccine has been assessed and approved on the basis of non-inferiority to 13vPCV (for which clinical efficacy data is available) based on immunogenicity studies. **Immunogenicity** In one RCT, Prevenar 20 and Prevenar 13 were each administered to 600 infants (n = 1204) born after 36 weeks gestation at the postnatal age of 42 -112 days as a 3-dose primary schedule to compare their immunogenicity. Immunoglobulin G (Ig G) concentration distributions for the 13 matched serotypes were similar between the two vaccines. The IgG responses to the 7 additional serotypes were substantially greater with Prevenar 20.[6] The non-inferiority of immunoglobulin G geometric mean concentrations criteria were met for 16 of the 20 vaccine serotypes one month after two vaccine doses, and 19 of the 20 serotypes one month after 3 vaccine doses.[6] Over 96 % participants had IgG concentrations greater than predefined levels to all serotypes except serotype 3 after completion of the vaccine schedule. Statistical non-inferiority criteria for primary objectives were missed for matched serotypes 6A, 6B, 9V and 23F after dose 2 and narrowly missed for serotype 6B after dose 3. However, robust opsonophagocytic activity, and boosting responses were observed following Prevenar 20 vaccination for all vaccine serotypes, including those missing statistical non-inferiority criteria.[6] In other randomised control trials, a four- dose schedule of Prevenar 20 was also well tolerated and elicited robust serotype-specific immune responses above protective levels in infants and children against pneumococcal disease due to the 20 vaccines serotypes.[7,8]

	In one RCT, a single booster dose of Prevenar 20 between 12 to 24 months of age after two doses of Prevenar 13 during infancy elicited protective level immune responses against the 7 additional serotypes and provided similar protection against the 13 serotypes matched with Prevenar 13.[9] These data suggest that transition from Prevenar 13 to Prevenar 20 after 12 months is effective and safe. There are currently no studies on immunogenicity of Prevenar in children with risk conditions.[3] In adults, pneumococcal and influenza antibody responses following co-administration of Prevenar 20 with quadrivalent influenza vaccine was non-inferior to either Prevenar 20 or influenza vaccines administered separately.[10] Modelling studies have postulated that replacing Prevenar 13 with Prevenar 20 is likely to have a substantial health benefit due to higher invasiveness of the additional serotypes covered by Prevenar 20. Primary vaccination with Prevenar 20 is estimated to further reduce pneumococcal disease and associated healthcare system and societal costs compared to Prevenar 13.[11,12] **Safety** Overall, Prevenar 20 is reported to have a similar safety/tolerability profile to Prevenar 13.[7,13,14] Some reports suggest fewer local reactions with Prevenar 20.[7] A large, randomised control trial involving administration of four doses of Prevenar 20 to 1000 infants and Prevenar 13 to 500 infants noted similar adverse events in both groups. No serious adverse events related to study vaccines were reported.[13]
Practice points	
References	1. https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2022-PI-02385-1. Accessed 25/08/2025. 2. https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2023-CMI-01428-1&d=20250825172310101. Accessed 25/08/2025. 3. https://immunisationhandbook.health.gov.au/vaccines/prevenar-20. Accessed 25/08/2025. 4. https://www.health.gov.au/sites/default/files/2025-06/national-immunisation-program-schedule.pdf. Accessed 25/08/2025. 5. https://immunisationhandbook.health.gov.au/resources/tables/table-catch-up-schedule-for-pcvs-for-aboriginal-and-torres-strait-islander-children-living-in-nsw-vic-tas-or-act-and-children-from-all-statesterritories-who-do-not-have-risk-conditions-for-pneumococcal-disease-aged. Accessed on 25/08/2025. 6. Korbal P, Wysocki J, Jackowska T, et al. Phase 3 Safety and Immunogenicity Study of a Three-dose Series of Twenty-valent Pneumococcal Conjugate Vaccine in Healthy Infants and Toddlers. Pediatr Infect Dis J. 2024 Jun 1;43(6):587-595. 7. Ishihara Y, Fukazawa M, Enomoto S, et al. A phase 3 randomized study to evaluate safety and immunogenicity of 20-valent pneumococcal conjugate vaccine in healthy Japanese infants. Int J Infect Dis. 2024 Apr; 141:106942. 8. Senders S, Klein NP, Tamimi N, et al. A Phase Three Study of the Safety and Immunogenicity of a Four-dose Series of 20-Valent Pneumococcal Conjugate Vaccine in Healthy Infants. Pediatr Infect Dis J. 2024 Jun 1;43(6):596-603. 9. Martinón-Torres F, Martinez SN, Kline MJ, Drozd J, et al. A phase 3 study of 20-valent pneumococcal conjugate vaccine in healthy toddlers previously vaccinated in infancy with 13-valent pneumococcal conjugate vaccine. Vaccine. 2025 Apr 19; 53:126931. 10. Cannon K, Cardona JF, Yacisin K, et al. Safety and immunogenicity of a 20-valent pneumococcal conjugate vaccine co-administered with quadrivalent influenza vaccine: A phase 3 randomized trial. Vaccine. 2023 Mar 24;41(13):2137-2146. 11. Rozenbaum MH, Huang L, Perdrizet J, et al. Cost-effectiveness of 20-valent pneumococcal conjugate vaccine in US infants. Vaccine. 2024 Jan 25;42(3):573-582 12. Choi YH, Bertran M, Litt DJ, et al Potential impact of replacing the 13-valent pneumococcal conjugate vaccine with 15-valent or 20-valent pneumococcal conjugate vaccine in the 1 + 1 infant schedule in England: a modelling study. Lancet Public Health. 2024 Sep;9(9): e654-e663. 13. Hajdu G, Hughes T, Ouedraogo GL, et al. Safety of a 4-Dose 20-Valent Pneumococcal Conjugate Vaccine Series in Infants: A Randomized Trial. Pediatrics. 2024 Nov 1;154(5): e2023065218. 14. Senders S, Klein NP, Lamberth E, et al. Safety and Immunogenicity of a 20-valent Pneumococcal Conjugate Vaccine in Healthy Infants in the United States. Pediatr Infect Dis J. 2021 Oct 1;40(10):944-951.

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