

Meningococcal vaccines

Newborn use only

2025

Alert	If possible, complete the primary course of MenACWY vaccination with the same vaccine brand. For people aged <10 years, Bexsero is the only registered Meningococcal B vaccine in Australia.																									
Indication	Primary immunisation against meningococcal disease.																									
Action	Induces antibodies against meningococcal A, C, W, Y and B serogroups.																									
Drug type	Vaccine.																									
Trade name	Meningococcal B vaccines: Bexsero (MenB-4C) – Recombinant protein based meningococcal serogroup B vaccine. Meningococcal ACWY vaccines: Menveo (MenACWY-CRM) - Quadrivalent meningococcal diphtheria conjugate vaccine. Nimenrix (MenACWY-TT) - Quadrivalent meningococcal tetanus toxoid conjugate vaccine. MenQuadfi (MenACWY-TT) - Quadrivalent meningococcal tetanus toxoid conjugate vaccine.																									
Presentation	Bexsero: 0.5 mL monodose pre-filled syringe Menveo: 0.5 mL monodose single vial containing ACWY or in 2-vial presentation requiring reconstitution with one vial containing MenA and the other Men CWY Nimenrix: 0.5 mL monodose vial with separate pre-filled syringe containing solvent. MenQuadfi: 0.5mL monodose vial.																									
Dose	<p>0.5 mL Intramuscular as follows: (Refer to practice points)</p> <p>Can be co-administered with other routine immunisations. Bexsero can also be administered separately to other vaccines, with a minimum 3-day interval to reduce the risk of fever.</p> <p><u>Meningococcal ACWY vaccine: (Free under the NIP for all infants from 12 months of age, and for all aged 6 weeks and older with specified medical risk conditions)</u></p> <table> <tr> <th>Age at commencement*</th><th>Vaccine brand</th><th>Doses</th></tr> <tr> <td>6 weeks – 5 months</td><td>Menveo, Nimenrix</td><td>3 doses (8 weeks between 1st and 2nd dose; 3rd dose at 12 months of age)</td></tr> <tr> <td>6-11 months</td><td>Menveo, Nimenrix</td><td>2 doses (2nd dose at 12 months of age or 8 weeks after 1st dose, whichever is later)</td></tr> <tr> <td>12-23 months</td><td>Menveo, Nimenrix, MenQuadfi</td><td>Menveo: 2 doses (8 weeks apart) Nimenrix: 1 dose MenQuadfi: 1 dose</td></tr> <tr> <td>*Travel to high-risk country</td><td colspan="2">Refer to the latest Australian Immunisation guidelines.</td></tr> </table> <p><u>Meningococcal B vaccine (Bexsero):* (Free under the NIP for First Nations infants aged 6 weeks to <2 years and all infants aged 6 weeks and older with specified medical risk conditions).</u></p> <table> <tr> <th>Age at commencement</th><th>Vaccine brand</th><th>Doses</th></tr> <tr> <td>6 weeks – 11 months</td><td>Bexsero</td><td>3 doses (8 weeks between 1st and 2nd dose; 3rd dose at 12 months of age or 8 weeks after 2nd dose, whichever is later)</td></tr> <tr> <td>12-23 months</td><td>Bexsero</td><td>2 doses (8 weeks apart)</td></tr> </table> <p><u>*3 doses of paracetamol, starting within 30 minutes prior to vaccine administration and subsequently 4-6 hours apart are recommended, regardless of whether fever is present.</u></p> <p><u>Infants with specified medical conditions with increased risk of IMD:</u> Refer to Australian Immunisation schedule (1)</p>		Age at commencement*	Vaccine brand	Doses	6 weeks – 5 months	Menveo, Nimenrix	3 doses (8 weeks between 1 st and 2 nd dose; 3 rd dose at 12 months of age)	6-11 months	Menveo, Nimenrix	2 doses (2 nd dose at 12 months of age or 8 weeks after 1 st dose, whichever is later)	12-23 months	Menveo, Nimenrix, MenQuadfi	Menveo: 2 doses (8 weeks apart) Nimenrix: 1 dose MenQuadfi: 1 dose	*Travel to high-risk country	Refer to the latest Australian Immunisation guidelines.		Age at commencement	Vaccine brand	Doses	6 weeks – 11 months	Bexsero	3 doses (8 weeks between 1 st and 2 nd dose; 3 rd dose at 12 months of age or 8 weeks after 2 nd dose, whichever is later)	12-23 months	Bexsero	2 doses (8 weeks apart)
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Dose adjustment	Therapeutic hypothermia: Not applicable ECMO: Not applicable. Renal impairment: No information. Hepatic impairment: No information.																									
Maximum dose	Not applicable.																									

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Total cumulative dose	Not applicable.
Route	Intramuscular.
Preparation	None required.
Administration	<ol style="list-style-type: none"> 1. May administer oral sucrose 2 minutes prior to injection (observe local pain policy). 2. Administer oral paracetamol within 30 minutes before Bexsero vaccine and can repeat 2nd and 3rd dose 4-6 hours apart. (1, 2, 3). 3. Follow product specific directions, as some products require reconstitution. 4. Shake syringe vigorously immediately prior to use to obtain a homogenous, white suspension. 5. Visual inspection for particulate matter and discoloration. 6. Administer by deep intramuscular injection to the anterolateral aspect of the thigh (slowly to reduce pain). 7. Administer on the opposite limb from other concurrently administered vaccines. 8. Register the vaccines with the Australian Immunisation Register 9. Register as per the local hospital policy. 10. Single use in one patient only
Monitoring	<ol style="list-style-type: none"> 1. Observe for 15 minutes after vaccination for any adverse events. 2. Pain: Refer to local pain relief policy. 3. Body temperature. 4. History of febrile convulsions: Infants should be closely followed up for 2-3 days for any convulsions.
Contraindications	<p>Anaphylaxis after a previous dose of any meningococcal vaccine.</p> <p>Anaphylaxis after any component of a meningococcal vaccine.</p> <p>Previous meningococcal disease is not a contraindication.</p> <p>Previous vaccination with the strain-specific MenB vaccine used in New Zealand (MeNZB) is not a contraindication to Bexsero.</p> <p>Previous vaccination with a quadrivalent polysaccharide meningococcal vaccine (<i>4vMenPV</i>; used previously in Australia) is not a contraindication to receiving any MenACWY vaccine.</p>
Precautions	<p>Acute illness or temperature greater than 38.5°C – postpone vaccine until neonatologist approves.</p> <p>Bexsero can be given separate to other routine vaccines, with a minimum interval of 3 days, to minimise the risk of fever.</p>
Drug interactions	MenACWY vaccines can be co-administered with most other vaccines.
Adverse reactions	<p>Bexsero: 26–41% develop fever $\geq 38^{\circ}\text{C}$, and 4–8% have fever $\geq 39^{\circ}\text{C}$. Temperatures are generally highest 6 hours after vaccination, decreased on day 2 and subsided by day 3. Other adverse effects included pain, tenderness, swelling, induration and erythema at the injection site, irritability, sleepiness, crying, change in appetite.</p> <p>Menveo: Frequency of adverse events are similar to other childhood vaccines. Fever in about 1%.</p> <p>Nimenrix: Mild injection site reactions in 30–50%. About 20% had a mild systemic reaction.</p> <p>Menactra: Most reactions are local injection site reactions.</p>
Compatibility	Not applicable.
Incompatibility	Not applicable.
Stability	Do not remove from refrigerator until time of administration. Expiry is found on packaging.
Storage	Store at 2°C to 8°C. Do not freeze. Protect from light. Storage should in line with national vaccine storage guidelines “Strive for 5”.
Excipients	<p><u>Bexsero</u>: sodium chloride, histidine, sucrose.</p> <p><u>Nimenrix</u>: Sucrose, trometamol, 0.9% Sodium chloride.</p> <p><u>Menactra</u>: Sodium chloride, dibasic and monobasic sodium phosphate.</p> <p><u>Menveo</u>: Sucrose, butyl rubber, potassium dihydrogen phosphate, dibasic and monobasic sodium phosphate, sodium chloride.</p>
Special comments	For Australian infants- Bexsero® is now funded under the National Immunisation Program (NIP) for Aboriginal and Torres Strait Islander infants from 6 weeks of age (1)
Evidence	<p>Efficacy</p> <p>Meningococcal B vaccine: Bexsero protects against most circulating meningococcal B strains. Around 75% of all meningococcal B strains that caused disease in Australia from 2007 to 2011 would be susceptible to vaccine-induced antibodies. (4) From 2013, the incidence of meningococcal W disease</p>

increased rapidly and the incidence of meningococcal Y disease increased steadily from 2015. (1) The data from United Kingdom suggest that vaccine effectiveness of 2 doses given at 2 and 4 months of age is 82.9%. (5) In fully vaccine eligible children aged under 5 years, the adjusted vaccine effectiveness against meningococcal group B disease was 52.7% with a two-dose priming schedule and 59.1% with a two-dose priming schedule plus a booster at 1 year. (6)

Meningococcal conjugate vaccines: Menveo, when given in a 3-dose schedule at 2, 4 and 12 months of age, more than 99% of children developed protection against meningococcal W and Y. (7) 97% of children aged 12–23 months who received Menveo developed a protective immune response to all 4 meningococcal serogroups after 2 doses. (8) Nimenrix, given in a 3-dose schedule at 2, 4 and 12 months of age, more than 99% of children developed protection against all 4 meningococcal serogroups after completion of the course. (9) In a recent review of four studies, MenACWY-TT administered as a three doses primary schedule at 2, 3, and 4 months of age or two doses schedule administered at 2 and 4 months of age were demonstrated to be immunogenic in more than 88 to 93 % of the subjects 1 month post primary vaccination. At 12-15 months after primary vaccination, > 65% subjects still demonstrated protective titres across the serogroups. (10)

Co-administration of MenACWY with other routine vaccines: In total, more than 4000 infants and toddlers have received DTaPHBV-IPV/Hib co-administered with a monovalent or quadrivalent meningococcal conjugate vaccine in the clinical studies. The data support co-administration of DTaP-HBV-IPV/Hib with monovalent or quadrivalent meningococcal conjugate vaccines. (10,15)

Co-administration of 4CMenB (Bexsero) with other routine vaccines: Currently, DTaP-HBV-IPV/Hib is the only hexavalent vaccine that has been evaluated in co-administration with 4CMenB. More than 3000 infants have received DTaP-HBV-IPV/Hib co-administered with 4CMenB and PCV7 in clinical trials. The majority of children achieved seroprotection/vaccine response. (15)

Hospitalised preterm infants: Greater than 98% of premature infants, given a Men C conjugate containing vaccine on a 2, 3 and 4 month schedule, develop serum bactericidal activity (SBA) of ≥ 8 within one to two months of vaccination. (13, 14, 16-18). A prospective study on Meningococcal C conjugate vaccine (Meningitec) has been studied in hospitalised preterm infants (median, 33 weeks; range, 24–36 and median birthweight 1717 g; range, 600–3406) given as primary schedule at 2, 3 and 4 months of age. Preterm infants achieved protective titres after primary immunization but waned significantly by 1 year of age. (12) Co-administration of Meningococcal C conjugate vaccine (MCC, Meningitec) with DTaP-Hib (Infanrix-Hib) in preterm infants <32 weeks gestation elicit immunogenic response to MCC similar to term infants, although Hib IgG geometric mean concentrations were low in these preterm infants. (13) However, co-administration of MCC with combined DT5aP-Hib-IPV elicited higher protective Hib IgG concentrations. (14)

There is an increase in adverse effects including temperature instability, decreased feeding and reduced activity in hospitalised preterm infants after 4CMenB vaccine (Bexsero) (19). No such increase in adverse effects were noted in them with Meningococcal C vaccine (meningitec) co-administered with DTaP-Hib vaccine. (20)

Safety

Both MenACWY-CRM and MenACWY-TT quadrivalent conjugate meningococcal vaccines do not suggest safety concerns in infants. (10,19)

There were no statistically significant differences in the incidences of local or general symptoms after DTaP-HBV-IPV/Hib and MenACWY-TT co-administration versus DTaP-HBV-IPV/Hib administered alone (20, 21). Groups were similar in terms of the occurrence of serious adverse effects (SAE). No SAEs were considered to be causally related to vaccination. (22)

Prophylactic paracetamol: Administration of 3 doses of paracetamol (first dose at the time of vaccine and subsequent doses 4-6 hours apart) to infants receiving DTaP-HBV-IPV/Hib with 4CMenB (Bexsero) and PCV7 reduced the incidence and severity of local and systemic adverse effects without impairing the immune response. (2, 3)

	Pharmacokinetics Not applicable to vaccines.
Practice points	<u>Australian National Immunisation Program</u> <ol style="list-style-type: none"> Any person from 6 weeks of age who wants to protect themselves against meningococcal disease is recommended to receive MenACWY vaccine and MenB vaccine. Eligible infant categories for free vaccines under the Immunisation program can be found on the latest immunisation guidelines. MenACWY vaccines and Men B vaccine (Bexsero) can be co-administered with other routine vaccines. MenB and MenACWY vaccines can be co-administered at any age. Of 3 available MenACWY vaccines: (a) Infants aged <12 months can receive either Menveo or Nimenrix, (b) children aged 12 months to 2 years can receive any of 3 brands. Follow the brand specific dosing schedule. For infants aged <6 months who are travelling to areas where meningococcal A disease is common and who are receiving Menveo, a 4-dose schedule (given as a 3+1 schedule) should be considered for optimal protection against serogroup A. Three primary doses should be given with an interval of 8 weeks between doses, followed by a 4th dose at 12 months age. If a person needs to receive Nimenrix and a vaccine containing tetanus toxoid (such as Infanrix hexa) co-administration of these vaccines is preferred. Nimenrix should be given as scheduled, even if it is being given shortly after a vaccine containing tetanus toxoid. Children <2 years of age have an increased risk of fever if Bexsero is co-administered with other routine vaccines. However, this is not a contraindication to co-administration of Bexsero with other vaccines. Bexsero can also be administered separately to other vaccines, with a minimum 3 day interval to reduce the risk of fever, and with prophylactic paracetamol.
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