

South Australian Neonatal Medication Guidelines

Meningococcal group B vaccine

Bexsero[®] (multicomponent, recombinant)

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Note:

This guideline provides advice of a general nature. This statewide guideline has been prepared to promote and facilitate standardisation and consistency of practice, using a multidisciplinary approach. The guideline is based on a review of published evidence and expert opinion.

Information in this statewide guideline is current at the time of publication.

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Health practitioners in the South Australian public health sector are expected to review specific details of each patient and professionally assess the applicability of the relevant guideline to that clinical situation.

If for good clinical reasons, a decision is made to depart from the guideline, the responsible clinician must document in the patient's medical record, the decision made, by whom, and detailed reasons for the departure from the guideline.

This statewide guideline does not address all the elements of clinical practice and assumes that the individual clinicians are responsible for discussing care with consumers in an environment that is culturally appropriate and which enables respectful confidential discussion. This includes:

- The use of interpreter services where necessary,
- Advising consumers of their choice and ensuring informed consent is obtained,
- Providing care within scope of practice, meeting all legislative requirements and maintaining standards of professional conduct, and
- Documenting all care in accordance with mandatory and local requirements

Synonyms

MenBV

Dose and Indications

Primary immunisation against invasive *Neisseria meningitidis* serogroup B disease

Intramuscular

0.5mL (Bexsero[®]) at 6 weeks, 4 months and 12 months of age

Provided they are medically stable and there are no contraindications to vaccination, preterm infants should receive vaccines according to the recommended schedule at their chronological age.

The attending clinician should assess medical stability in extremely preterm infants born <28 weeks gestation before vaccination, with reference to Neonatal Unit policy.

Paracetamol is recommended for prophylaxis of post-immunisation pyrexia in children less than 2 years of age. The first dose of paracetamol is recommended within the 30-minute period prior to, or as soon as practicable after vaccination. This is followed by two further doses of paracetamol (see Paracetamol guideline for dosing and frequency). All doses are recommended regardless of the presence of fever.



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Preparation and Administration

Intramuscular

Bexsero[®] is given by deep intramuscular injection, in the left anterolateral thigh.

Bexsero[®] can be safely administered with other National Immunisation Program (NIP) vaccines. However, administer Bexsero[®] in a separate thigh to other NIP vaccines. E.g. at the 6 week and 4 month NIP schedule points, administer Bexsero[®] in the left thigh and Prevenar 13[®] and Infanrix Hexa[®] in the right thigh (injections to be separated by 2.5cm).

Shake well before use. Give injection slowly to reduce pain.

Bexsero[®] is presented as a 0.5mL white opalescent liquid suspension in a prefilled syringe.

Store in a refrigerator (2°C - 8°C). Do not freeze. Protect from light.

Administration of Bexsero[®] should be postponed in infants who are medically unstable or suffering from an a febrile illness.

Record the vaccination in the patient's My Health and Development Record (blue book) and Australian Immunisation Register (AIR).

Adverse Effects

Common

Bexsero has an acceptable safety and tolerability profile based on clinical trial data. Fever ($\geq 38^{\circ}\text{C}$) is very common.

Sleepiness, unusual crying, poor appetite, irritability, diarrhoea, vomiting, rash, irritability, arthralgia or myalgia presenting as pain

Injection site pain or tenderness (may be severe, defined as crying when injected limb is moved), erythema, swelling

Uncommon

Seizures (including febrile seizures), pallor

Rare

Kawasaki syndrome, allergic reaction including anaphylaxis

Post marketing reports include allergic reactions, hypotonic-hyporesponsive episode, injection site reactions, extensive swelling of the vaccinated limb

Monitoring

- > Monitor for apnoea and bradycardia for 48 hours in preterm infants at risk of apnoea
- > Monitor temperature 4 to 6 hourly in preterm infants for 48 hours post immunisation
- > Observe injection site for reaction



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Practice Points

- > There is very limited safety data in preterm infants, suggesting no increase in risk of apnoea, bradycardia and desaturation after immunisation with Meningococcal B vaccination at 8 weeks of age. However due to the known increased risk of fever with Bexsero[®], attending neonatologist should assess medical stability in extremely preterm infants <28 weeks gestation before vaccination.
- > Because of the increased risk of fever, including high fever, after receiving Bexsero[®], children <2 years of age are recommended to receive prophylactic paracetamol with every dose. This is an exception to the general recommendation to not routinely give paracetamol at the time of vaccination.
- > Notify any serious, uncommon or unexpected adverse events possibly related to immunisation.
- > Duration of protection is unknown.

References

- > National Immunisation Program, South Australia Schedule, October 2018
- > Kent A. Beebeejaun K, Braccio S et al. Safety of meningococcal group B vaccination in hospitalised premature infants, Archives of Disease in Childhood. Fetal and Neonatal Edition, 2018, 0, F1-F5
- > Mukherjee D, Mukherjee A, Rajai A et al, G264(P) Menb(bexsero) immunisation side effects in extremely premature infants (<28 weeks), Archives of Disease in Childhood, 2018; 103(suppl 1); A1-A212
- > Vesikari T, Esposito S, Prymula R, et al. Immunogenicity and safety of an investigational multicomponent, recombinant, meningococcal serogroup B vaccine (4CMenB) administered concomitantly with routine infant and child vaccinations: results of two randomised trials. The Lancet 2013;381:825-35.

Document Ownership & History

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