

Hepatitis B vaccine

5 micrograms/0.5 mL (H-B-Vax II Paediatric[®]),
10 micrograms/0.5mL (Engerix-B Paediatric[®])

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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



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Synonyms

Hep B immunisation

Dose and Indications

Primary immunisation against and prevention of vertical transmission of hepatitis B virus

Intramuscular

5micrograms / 0.5 mL (H-B-VAX II[®] Paediatric)

OR

10micrograms / 0.5mL (Engerix-B[®] Paediatric)

Should be given to all infants as soon as possible after birth, and within 7 days

Clinician discretion should be applied for the suitability of birth dose for infants born <32 weeks gestation and/or <2000g, where mother is hepatitis B surface antigen-negative, with reference to Neonatal Unit policy.

Infants are recommended to receive 4 doses of hepatitis B vaccine:

- 1 dose of monovalent paediatric formulation hepatitis B vaccine at birth
- 3 doses of a paediatric hepatitis B-containing vaccine at 6 weeks, 4 months and 6 months (see Infanrix hexa[®] guideline)

For babies born <32 weeks gestation and/or <2000g, a booster dose (H-B-VAX II[®] Paediatric or Engerix-B[®] Paediatric) is also given at 12 months regardless of administration of birth dose (unless serology confirms infant protected – see monitoring)

For all infants born to mothers who are hepatitis B surface antigen-positive, give dose as soon as possible after birth (preferably within 12 hours of birth) administered at the same time as hepatitis B immunoglobulin in the opposite thigh (see Hepatitis B Immunoglobulin guideline)

Preparation and Administration

Intramuscular

Shake vial well before use and administer dose via deep intramuscular (IM) injection into anterolateral thigh.

Record vaccine batch number on medication chart.

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



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Adverse Effects

Common

Transient local pain, redness, swelling and warmth

Infrequent

Low-grade fever

Rare

Systemic reactions such as rash, bronchospasm, and anaphylaxis are unlikely to occur in neonates

Monitoring

- > **All infants born to hepatitis B surface antigen positive mothers:**
 - > Hepatitis B surface antibodies (anti-HBs) and HBsAg concentrations should be measured 3 months after completing the primary course (i.e. 3 months after 6 month vaccination). **Do not test the infant before 9 months of age**, to avoid detecting anti-HBs from the HBIG given at birth.
 - > If anti-HBs levels are adequate (≥ 10 mUnit/mL) and HBsAg is negative, then the infant is considered to be protected.
 - > If anti-HBs titre is <10 mUnit/mL or HBsAg is positive, refer to Infectious Diseases
- > For infants born <2000 g and/or <32 weeks gestation (excluding those born to hepatitis B surface antigen positive mothers – see above):
 - > There is no need to measure the hepatitis B surface antibody (HBs) titre after the primary series. However, if measuring the antibody titre, this should be done at least 1 month after the 6-month dose.
 - > If anti-HBs titre is ≥ 10 mUnit/mL then the infant is considered to be protected.
 - > If the anti-HBs titre is <10 mUnit/mL, give a booster dose at 12 months and re-check antibody titre at least 1 month after booster

Practice Points

- > There are two monovalent hepatitis B vaccines approved for use in Australia, H-B-Vax II Paediatric[®] and Engerix-B Paediatric[®]. Whilst switching brands is not recommended, the two vaccines may be used interchangeably. Even though they contain different Hepatitis B surface Antigen content, they are considered equivalent (i.e. 0.5mL injection is given irrespective of which product is used).
- > All neonates born to mothers who are positive to the hepatitis B surface antigen, regardless of gestation, must receive a dose of the hepatitis B vaccine with a dose of the hepatitis B immunoglobulin, within 12 hours of birth (see Hepatitis B Immunoglobulin guideline)
- > Where mother is hepatitis B surface antigen positive, documentation of immunity to hepatitis B in the infant is required by measuring hepatitis B antibodies 3 months after the 6 month vaccination (see monitoring)



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- > This injection is for INTRAMUSCULAR injection. The vaccine may be given via subcutaneous injection to patients at risk of haemorrhage from IM injection. Consider serological testing to confirm protection status.
- > Caution in patients with severely compromised cardiopulmonary status. Delay use in patients with a serious active infection, unless this is thought to put the patient at significant risk.
- > If the mother has a known blood borne virus, clean the limbs prior to administration
- > **For infants who require a booster dose, it is recommended that this is flagged in the patient’s My Health and Development Record (blue book).**

References

- > Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook, Australian Government Department of Health, Canberra, 2018, immunisationhandbook.health.gov.au.
- > D’Angio C, Active immunization of premature and low birth-weight infants: a review of immunogenicity, efficacy, and tolerability, 2007, Paediatric Drugs, 9(1): 17-32
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