Hepatitis B vaccine
Newborn use only

2021

Alert	All neonates (preterm or term) born to hepatitis B positive mothers must be given a dose of monovalent hepatitis B vaccine AND hepatitis B immunoglobulin (HBIG) at birth. These should both be given on the day of birth, at the same time but in separate thighs.
Indication	Primary immunisation of ALL infants against infection caused by the hepatitis B virus.
Action	Stimulates the production of antibodies to confer protection against the hepatitis B virus.
Drug type	Vaccine.
Trade name	H-B-VAX II Paediatric - for immunisation at birth. Engerix-B Paediatric − for immunisation at birth. Infanrix Hexa− for immunisation at 6 weeks-2 months, 4 and 6 months of age. Refer to Infanrix Hexa formulary.
Presentation	H-B-VAX II paediatric formulation: 5 microgram Hepatitis B surface antigen (HBsAg)/0.5 mL prefilled syringe or vial. Engerix-B paediatric formulation: 10 microgram HBsAg/0.5 mL prefilled syringe. Infanrix Hexa: 10 microgram HBsAg/0.5 mL suspension for injection (contains multiple actives).
Dose	0.5 mL IM. Should be given to all infants as soon as possible after birth. **The first dose must be given within 7 days of life**. A total of four doses should be administered at either: − Birth, 6 weeks -2 months, 4 months and 6 months OR − Birth, 6 weeks -2 months, 4 months and 12 months* *Hepatitis B vaccine is administered as a component of Infanrix-Hexa at 6 weeks to 2 months, 4 and 6 months. Babies born at < 32 weeks gestation or with a birth weight < 2000 g, are recommended to have their vaccine given at birth, 6 weeks -2 month, 4 and 6 months of age and either: − Measure hepatitis B antibodies at 7 months of age and give a booster at 12 months of age if antibody titre is < 10 mUnits/mL OR − Give a booster at 12 months without measuring antibody titre.
Dose adjustment	Therapeutic hypothermia – No information. ECMO – No information. Renal impairment – No information. Hepatic impairment – No information.
Maximum dose	
Total cumulative dose	
Route	IM
Preparation	No preparation required for H-B-Vax II and Engerix-B. Refer to Infanrix Hexa formulary for advice on preparation.
Administration	IM injection into the anterolateral thigh. Give at a separate site from other concurrently administered IM injections. Record details of vaccination in patient's Personal Health Record ('Blue Book'). Complete the Australian Immunisation Register (AIR) and the NSW Neonatal Hepatitis B Vaccination Program Form. Record vaccine batch number on the medication chart.
Monitoring	Hepatitis B surface antigens and hepatitis B surface antibodies should be measured in infants born to mothers with chronic hepatitis B infection 3 to 12 months after completing the primary vaccine course.
Contraindications	Postpone vaccination in significant acute illness or temperature > 38.5°C. Severe thrombocytopenia or a coagulation disorder. Anaphylaxis following a previous dose of any hepatitis B vaccine. Hypersensitivity to any vaccine component.
Precautions	
Drug interactions	
Adverse reactions	Swelling, tenderness. Fever can occur in 0.6–3.7% of cases.
Compatibility	Not applicable.
Incompatibility	Do not mix with any other vaccines in the same syringe or vial.
Stability	Refer to expiry date on the label and packaging.

	Discard if the vaccine has been frozen. Follow local cold chain guidelines and Department of Health National Vaccine Storage 'Strive for 5' Guidelines for management of vaccines during cold chain breaches. [2]
Storage	Store between 2 and 8°C. Protect from light.
Excipients	**Engerix-B:** Aluminium hydroxide 0.25 mg (adsorbent), dibasic sodium phosphate dihydrate, monobasic sodium phosphate, sodium chloride, water for injections, traces of polysorbate 20. H-B-VAX II paediatric formulation: Aluminium hydroxyphosphate sulfate 0.25 mg (adsorbant), borax, sodium chloride, water for injection. **Infanrix-Hexa:** Lactose, medium 199 (as stabiliser containing amino acids, mineral salts, vitamins and other substances), sodium chloride, aluminium hydroxide, aluminium phosphate, water for injections and the following residues: potassium chloride, polysorbate 20 and 80, formaldehyde, glycine, dibasic sodium phosphate dihydrate, monobasic potassium phosphate, neomycin sulfate and polymyxin B sulfate.
Special comments	Due to concerns regarding aluminium content in hepatitis B vaccines, practitioners may elect not to give hepatitis B vaccine at birth for infants < 28 weeks. (ANMF consensus)
Evidence	**Australian Technical Advisory Group on Immunisation (ATAGI) recommendations (1)** 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 2, 4 and 6 months of age (usually provided as DTPa-hepB-IPV-Hib [diphtheria-tetanus-acellular pertussis, hepatitis B, inactivated poliovirus, Haemophilus influenzae type b]). Infants can receive the dose scheduled at 2 months of age as early as 6 weeks of age. They should still receive their next scheduled doses at 4 months and 6 months of age. **Rationale for the birth dose** The rationale for the birth dose for all newborn infants is to prevent: 1. vertical transmission from a mother with chronic hepatitis B, recognising that there may be errors or delays in maternal testing, reporting, communication or appropriate response 2. horizontal transmission to the infant in the first months of life from people with chronic hepatitis B who are household or other close contacts Newborns should receive the birth dose as soon as they are medically stable, and preferably within 24 hours of birth, but the vaccine can be given within the first 7 days of life. Every effort should be made to give the vaccine before the baby is discharged from the obstetric hospital or delivery unit. A 3-dose schedule of DTPa-hepB-Hib-IPV (diphtheria-tetanus-acellular pertussis, hepatitis B, inactivated poliovirus, Haemophilus influenzae type b) given at 2, 4 and 6 months of age in a clinical trial was immunogenic, with more than 97% of children developing protection to hepatitis B antigen. A 3-dose schedule at birth, 1–2 months and 6–18 months of age is equally as immunogenic as the recommended Australian schedule above. Such schedules are often used overseas. Children born overseas who have received hepatitis B vaccine in this 3-dose schedule are considered to have completed the primary vaccination course. Longer intervals between doses do not affect the immunogenicity of hepatitis B vaccine. The minimum interval between the 1st and 3rd doses of a 3-dose primary schedule is 4 months. This means that a shortened 3-dose schedule provided at either 0, 1, 4 months or 0, 2, 4 months is acceptable. A standard 3-dose schedule induces protective levels of neutralising antibody against hepatitis B virus in more than 90% of healthy adults. Seroconversion occurs in approximately 30–55% of people after the 1st dose, increasing to 75% of people after the 2nd dose. The 3rd dose is needed to increase the percentage of people who respond and to provide long-term protection. More compressed 3-dose schedules, such as 0, 1, 3 months, are not recommended. These compressed schedules are associated with lower peak levels of protective antibodies and shorter duration of antibody persistence at levels of ≥10 mIU per mL.

	Low-birthweight and preterm newborns do not respond as well to hepatitis B–containing vaccines as full-term infants. Low-birthweight infants (<2000 g) and/or infants born at <32 weeks gestation (regardless of weight) are recommended to receive 5 doses including the 4-dose schedule at 0 (birth), 2, 4 and 6 months of age, followed by either: • giving a booster of a hepatitis B–containing vaccine at 12 months of age (without measuring the antibody titre), or measuring the level of antibody to hepatitis B surface antigen at 7 months of age; if the antibody titre is <10 mIU per mL, they should receive a booster at 12 months of age (because of a better immunogenic response at this age compared with a younger age).
Practice points	
References	1. Hepatitis B. Australian Immunisation Handbook. Accessed on 10 December 2020. 2. Engerix-B (Paediatric) Product Information by GlaxoSmithKline. Accessed on 25/03/21 3. H-B-Vax II (Paediatric) Product Information by Seqirus. Accessed on 25/03/21 4. Australian Government Department of Health and Aging. National Vaccine Storage Guideline-Strive for Five. 2nd Edition. 2013.

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