

Alert	All neonates (preterm or term) born to hepatitis B positive mothers must be given a dose of hepatitis B vaccine AND hepatitis B immunoglobulin at birth.
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	HB-Vax-II– for immunisation at birth. Infanrix Hexa– for immunisation at 2,4 and 6 months of age. Engerix-B– for immunisation at birth, 2,4 and 6 months of age.
Presentation	HB-Vax-II– 5 microg/0.5 mL Infanrix Hexa– 10 microg/0.5 mL Engerix-B Thiomersal Free Paediatric Formulation– 10 microg/0.5 mL
Dosage / Interval	0.5 mL IM. Should be given to all infants as soon as possible after birth. The greatest benefit is seen when the first dose is administered within 24 hours. The first dose must be given within 7 days. A total of four doses should be administered at either: – Birth, 2 months, 4 months and 6 months OR – Birth, 2 months, 4 months and 12 months Babies born at < 32 weeks gestation or with a birth weight < 2000 g, are recommended to have their vaccine given at 0, 2, 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. Record details of vaccination in patient's Personal Health Record ('Blue Book') and complete Australian Community Immunisation Register records and complete a NSW Neonatal Hepatitis B Vaccination Program Form. Record vaccine batch number on the medication chart.
Route	IM
Administration	IM injection. Shake well before use. Give at a separate site from other concurrently administered vaccines/IM injections.
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. IM injections should not be given if there is severe thrombocytopenia or a coagulation disorder.
Adverse Reactions	Swelling, tenderness. Fever can occur in 0.6–3.7% of cases.
Storage	Store between 2 and 8°C. Do NOT freeze as this reduces potency. Storage above or below the recommended temperature may decrease potency.

Special Comments	<p>Preterm neonates < 2000 g or < 32 weeks do not respond as well to hepatitis B vaccine as full term babies. They should have the usual dosing schedule and then consider a booster dose at 12 months.</p> <p>If the birth dose is not administered within 7 days of life a primary 3-dose course should be administered at 2, 4 and 6 months of age; no catch up dose is required.</p> <p>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.</p>
Evidence summary	To be updated
References	<ol style="list-style-type: none"> 1. Australian Technical Advisory Group on Immunisation. The Australian Immunisation Handbook. 10th ed. Canberra: Australian Government Department of Health, 2013. 2. MIMS Australia, H-B-Vax II paediatric, full product information (accessed 17/09/2014).

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