Hepatitis B immunoglobulin

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 one dose of 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	Prophylaxis in infants born to Hepatitis-B surface antigen (HBsAg) positive mothers.
Action	Human hepatitis B immunoglobulin. At least 98% of the protein is immunoglobulins (mainly IgG), with a hepatitis B antibody titre of not less than 100 IU/mL. Confers immediate passive immunity to hepatitis B infection.
Drug type	Immunoglobulin.
Trade name	Hepatitis B Immunoglobulin-VF (1) Available from the Blood Bank
Presentation	100 Unit/mL vial.
Dose	100 Units IM as a single dose.
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	Not applicable
Administration	IM injection in anterolateral thigh. The product should be brought to room temperature before use and injected immediately. Administer within 12 hours after birth. **DO NOT ADMINISTER IV** If the product appears turbid or contains any sediment it must not be used. Record details of the vaccination in patient's Personal Health Record ("Blue Book"). Record batch number on the medication chart. Record injection sites of concurrently administered vaccines to allow any local reactions to be attributed to the appropriate antigen.
Monitoring	Injection site for local reaction Hepatitis B surface antibodies (anti-HBs) and HBsAg concentrations should be measured in infants born to mothers with chronic hepatitis B infection 3 to 12 months after completing the primary vaccine course. Testing should not be performed before 9 months of age to avoid detection of anti-HBs from hepatitis B immunoglobulin given at birth. If anti-HBs levels are adequate (≥ 10 mUnit/mL) and HBsAg is negative, then the infant is considered to be protected.
Contraindications	Severe thrombocytopenia or bleeding disorder. Isolated IgA deficiency.
Precautions	Live attenuated virus vaccines: If Hepatitis B Immunoglobulin-VF is administered within two weeks of vaccination with a live attenuated virus vaccine, the efficacy of the vaccine may be compromised. Consideration should be given to re-vaccination approximately three months after Hepatitis B Immunoglobulin-VF was given.
Drug interactions	
Adverse reactions	Local pain and tenderness at injection site. Systemic reactions are rare but may include urticaria, angioedema, erythema, low grade fever.
Compatibility	
Incompatibility	No information
Stability	Refer to expiry date on the label and packaging.
Storage	Store between 2 and 8°C. Do not freeze. Protect from light.(1)
Excipients	Glycine
Special comments	
Evidence	Mother-to-child transmission, occurring during the perinatal period, is the most important cause of chronic infection, accounting for 35%–50% of carriers.(2) The risk of infection in infants born to

	HBsAg+/HBeAg+ mothers is considerably higher compared with those born to HBsAg+/HBeAg-ve mothers.(3-5) The combined use of vaccine and HB immunoglobulin (HBIG) within 24 h of birth is reported to reduce the risk of chronic HB infection to 10%–15% for infants born to **HBeAg+** mothers.(6) Hepatitis B vaccine alone or with hepatitis B immunoglobulin in neonates of **HBsAg+/HBeAg-** mothers Systematic review of 9 studies including 4 randomised controlled trials found no difference in the occurrence of hepatitis B infection, between neonates who received vaccine only, compared with those who received both vaccine and HBIG.(7) There was also no difference in seroprotection rate between 2 groups. One of the studies included in this review reported fulminant hepatic failure in 1/1050 (0.09%) of the neonates who were immunized with HB vaccine only, compared with none of the neonates 0/723 (0%) who were immunized with the combination of HB vaccine and HBIG.(7) This study performed the cost–benefit analysis for preventing fulminant hepatic failure, and favoured the co-administration of HB vaccine and HBIG.
Practice points	**Australian Technical Advisory Group on Immunisation (ATAGI) recommendations (8)** All newborns of mothers known to have chronic hepatitis B must receive both: (1) a birth dose of monovalent hepatitis B vaccine and (2) hepatitis B immunoglobulin (HBIG) These should both be given on the day of birth, at the same time but in separate thighs. Infants should receive HBIG immediately after birth — preferably within 12 hours of birth and certainly within 48 hours. Its efficacy decreases markedly if given more than 48 hours after birth. Give the dose of monovalent hepatitis B vaccine preferably within 24 hours of birth, and definitely within 7 days. This regimen results in seroconversion rates of more than 90% in neonates, even with concurrent administration of HBIG. Do not delay vaccination beyond 7 days after birth, because vaccination alone is reasonably effective in preventing infection if it is given early enough. Infants should receive 3 subsequent doses of a hepatitis B–containing vaccine at 2, 4 and 6 months of age, so that they receive a total of 4 doses of hepatitis B–containing vaccines. Measure levels of hepatitis B surface antigen (HBsAg) and anti-HBs (antibody to HBsAg) in infants born to mothers with chronic hepatitis B 3–12 months after completing the primary vaccine course. Do not test the infant before 9 months of age, to avoid detecting anti-HBs from the HBIG given at birth. The infant is protected against hepatitis B if: anti-HBs levels are adequate (≥10 mIU per mL) and HBsAg is negative
References	1. Hepatitis B Immunoglobulin-VF - Product information by CSL Behring. Accessed on 14 December 2020. 2. Yao J. Perinatal transmission of hepatitis B virus infection and vaccination in China. Gut. 1996;38(Suppl 2):S37-S8. 3. Akhter S, Talukder M, Bhuiyan N, Chowdhury T, Islam MN, Begum S. Hepatitis B virus infection in pregnant mothers and its transmission to infants. The Indian Journal of Pediatrics. 1992;59(4):411-5. 4. BEASLEY RP, TREPO C, STEVENS CE, SZMUNESS W. The e antigen and vertical transmission of hepatitis B surface antigen. American journal of epidemiology. 1977;105(2):94-8. 5. Okada K, Kamiyama I, Inomata M, Imai M, Miyakawa Y, Mayumi M. e antigen and anti-e in the serum of asymptomatic carrier mothers as indicators of positive and negative transmission of hepatitis B virus to their infants. New England Journal of Medicine. 1976;294(14):746-9. 6. Chang M-H, editor Hepatitis B virus infection. Seminars in fetal and neonatal medicine; 2007: Elsevier. 7. Chen HL, Lin LH, Hu FC, Lee JT, Lin WT, Yang YJ, et al. Effects of maternal screening and universal immunization to prevent mother-to-infant transmission of HBV. Gastroenterology. 2012;142(4):773-81. e2. 8. Australian Immunisation Handbook. Hepatitis B. Accessed on 22 March 2021.

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