

<b>Indication</b>	Passive immunisation of newborns whose mothers have acute hepatitis B infection at the time of delivery or who are hepatitis B surface antigen (HBsAg) positive.
<b>Action</b>	Confers immediate passive immunity due to the injection of pre-formed antibodies.
<b>Drug Type</b>	Immunoglobulin.
<b>Trade Name</b>	Hepatitis B Immunoglobulin-VF
<b>Presentation</b>	100 Unit/mL ampoule. Available from the blood bank.
<b>Dosage/Interval</b>	100 Units single dose.
<b>Route</b>	IM ONLY in the anterolateral thigh.
<b>Administration</b>	Administer as a separate injection within 12 hours after birth at the same time as the hepatitis B vaccine (should be given in the other thigh). Efficacy decreases > 48 hours from birth. DO NOT ADMINISTER IV because of the risk of serious systemic reactions. 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.
<b>Monitoring</b>	Monitor injection site. 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 ( $\geq 10$ mUnit/mL) and HBsAg is negative, then the infant is considered to be protected.
<b>Contraindications</b>	Severe thrombocytopenia or bleeding disorder. Isolated IgA deficiency.
<b>Adverse Reactions</b>	Local pain and tenderness at injection site. Systemic reactions are rare but may include urticaria, angioedema, erythema, low grade fever.
<b>Storage</b>	Store between 2 and 8°C. Do not freeze. Protect from light.
<b>Special Comments</b>	Nil
<b>Evidence summary</b>	To be updated.
<b>References</b>	1. Australian Technical Advisory Group on Immunisation. The Australian Immunisation Handbook. 10th ed. Canberra: Australian Government Department of Health, 2013. 2. MIMS Australia, Hepatitis B Immunoglobulin-VF full product information (Accessed 17 <sup>th</sup> September 2014).

<b>Original version Date: 08/08/2015</b>	<b>Author: NeoMed Consensus Group</b>
<b>Current Version number: 1</b>	<b>Version Date: 08/08/2015</b>
<b>Risk Rating: High</b>	<b>Due for Review: 08/08/2017</b>
<b>Approval by: As per Local Policy</b>	<b>Approval: RHW Quality &amp; Patient Safety Committee 19/11/15</b>