### Indication
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.

### Action
Confers immediate passive immunity due to the injection of pre-formed antibodies.

### Drug Type
Immunoglobulin.

### Trade Name
Hepatitis B Immunoglobulin-VF

### Presentation
100 Unit/mL ampoule. Available from the blood bank.

### Dosage/Interval
100 Units single dose.

### Route
IM ONLY in the anterolateral thigh.

### Administration
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.

### Monitoring
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.

### Adverse Reactions
Local pain and tenderness at injection site. Systemic reactions are rare but may include urticaria, angioedema, erythema, low grade fever.

### Storage
Store between 2-8°C. Do not freeze. Protect from light.

### Special Comments
Nil

### Evidence summary
To be updated.

### References

---

Original version Date: 08/08/2015
Current Version number: 1
Risk Rating: Medium
Approval by: JHCH CQ&PCC

Author: Neonatal Medicines Formulary Consensus Group
Version Date: 08/08/2015
Due for Review: 26/02/2021
Approval Date: 26/02/2019

---

This is a printed copy. Refer to HNE PPG Intranet site for the most up to date version.