

This information was up to date at the time of release to the Heads of Midwifery.

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Updating arrangements for the formulary should be decided upon and implemented at a local level.

Hepatitis B immunoglobulin - human (HBIG) Neonate	
Legal status (GSL, P or POM on exemption list, or PGD)	<ul style="list-style-type: none"> ▪ POM - midwife may administer as medicine is on midwives exemptions list
Patient group	Babies requiring passive immunisation against hepatitis B.
Clinical indication	Immunoprophylaxis of hepatitis B in the newborn of a hepatitis B virus carrier-mother - see table below as not required if >1500g and mother known to be anti-HBe positive.
Pharmacology (Onset and duration of action where appropriate)	<p>It contains antibodies to hepatitis B virus and provides passive immunity. It can give immediate but temporary protection against hepatitis B.</p> <p>It is recommended only in high-risk situations such as babies likely to be exposed to the hepatitis B virus.</p> <p>It is given at the same time as hepatitis B vaccine and does not affect the development of active immunity.</p>
Pharmaceutical form, strength, route of administration	<p>Solution for injection in vials containing nominally 200 or 500 international units (IU). The concentration is approximately 100 IU/ml. The correct volume to give the stated potency is overprinted on the label.</p> <p>For intramuscular injection.</p> <p>NB: There are other concentrations or presentation but these are not suitable for neonates.</p>
Dose, frequency and maximum number of doses or period of time for administration or supply	<p>200 international units as a single dose as soon after birth as possible ideally within 24 hours.</p> <p>This is a high volume to give to a neonate- ideally split the dose and site and have 2 people administering simultaneously. It may be necessary to have 1 person administer the split dose in sequence - use 2 different sites.</p> <p>Administer at separate site to hepatitis B vaccine.</p>
Contra-indications/exclusion criteria	<ul style="list-style-type: none"> ▪ hypersensitivity to human immunoglobulins ▪ known hypersensitivity to any component of the medicine
Cautions and action that will be taken if a caution applies	<ul style="list-style-type: none"> ▪ ensure that it is not administered into a blood vessel, because of the risk of shock ▪ check for and document any allergies ▪ check and document past medical and drug history and current medication to ascertain potential for overdose ▪ if a caution applies consult with a doctor ▪ document consultation in baby record

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Medicine interactions and action that will be taken if a patient is taking a medicine that may interact	<ul style="list-style-type: none"> ▪ live vaccines ▪ may interfere with serological testing for example Coombs' test ▪ if there is drug interaction, consult with a doctor before administration or supply ▪ document consultation in neonatal record ▪ refer to current BNF for latest information on interactions
Potential adverse reactions and side effects including actions to be taken if adverse drug reaction is suspected	<ul style="list-style-type: none"> ▪ <i>true allergic reactions including anaphylaxis reactions to HBIG are rare and more likely in patients with antibodies to IgA or who have had an allergic reaction after blood transfusion or treatment with plasma derivatives</i> ▪ <i>pain at injection site and rarely local induration</i> ▪ <i>risk of transmission of virus infection</i> ▪ <i>in adults chest pain, dyspnoea, tremor, dizziness, facial oedema, glossitis, buccal ulceration and arthralgia</i> ▪ <i>on labour</i> Nil ▪ <i>on the neonate</i> Nil ▪ <i>on breast feeding</i> Nil ▪ <i>if a serious adverse reaction is suspected please report to the MHRA Yellow Card Scheme http://yellowcard.mhra.gov.uk/</i>
Overdose	<ul style="list-style-type: none"> ▪ no information available ▪ immediate assessment/treatment is essential - refer to medical staff ▪ manage in accordance with established treatment guidelines or see BNF overdose section ▪ for further advice contact National Poisons Centre 0344 892 0111
Action if patient declines	<ul style="list-style-type: none"> ▪ refer to authorised prescriber or doctor ▪ document in baby record
Additional advice and information	<ul style="list-style-type: none"> ▪ record the name and batch number of product in the baby record ▪ record information on Hepatitis B Postnatal Notification forms and send to Child Health Information Systems (SIRS) and Public Health ▪ supply the manufacturer's patient information leaflet to the parent if requested
Patient monitoring arrangements during and after treatment and follow-up required	<p>Advise GP that serology testing is required 2-4 months after completion of the course of Hepatitis B vaccination.</p>

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Particular storage requirements

- store 2°C - 8°C
- can be stored below 25°C for up to one week
- do not freeze
- do not use if solution is cloudy or has deposits
- bring to room temperature before administration
- dispose of any used product or waste material in accordance with local guidelines

References

1. Summary of Product Characteristics
<http://www.medicines.org.uk> for Human Hepatitis B immunoglobulin (BPL) (last revised 5.10.2016)
accessed 27.12.2019
2. <http://www.bnf.org>
3. Immunisation against infectious diseases: Green Book.
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/628602/Greenbook_chapter_18.pdf Updated 18.11.2019 Accessed 27.12.2019

Additional information on Hepatitis B immunoglobulin and Hepatitis B vaccine

Hepatitis B vaccine is used to prevent infection in babies at risk of contracting hepatitis B. It is either used alone or in conjunction with hepatitis B immunoglobulin. See table below

Hepatitis B status of Mother	Baby should receive	
	Hepatitis B vaccine	HBIG
Mother is HBsAg positive and HBeAg positive	Yes	Yes
Mother is HBsAg positive, HBeAg negative and anti-HBe negative	Yes	Yes
Mother had acute hepatitis B during pregnancy	Yes	Yes
Mother is HBsAg positive and anti-HBe positive	Yes	No
A woman who is HBsAg seropositive and known to have an HBV DNA Level equal or above 1×10^6 IU/ml in any antenatal sample during this pregnancy (regardless of HBeAg and anti-HBe status)	Yes	Yes
Mother is HBsAg positive and baby weighs 1500g or less	Yes	Yes

Table taken from Immunisation against infectious diseases: Green Book

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/628602/Greenbook_chapter_18.pdf

Updated 18.11.2019 Accessed 27.12.2019

