

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 vaccine 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 born to mothers who are chronically infected with hepatitis B or who have had acute hepatitis B infection during pregnancy.
Clinical indication	Active immunisation of babies against hepatitis B.
Pharmacology (Onset and duration of action where appropriate)	Hepatitis B vaccine contains inactivated hepatitis B virus surface antigen (HBsAg) and when administered evokes an immune response. If vaccination is started at birth it can prevent perinatal transmission of hepatitis B in over 90% of cases.
Pharmaceutical form, strength, route of administration	Suspension for injection. 20microgram/ml (Energix B [®]) vial or pre-filled syringes. Or 10microgram/ml (HBvaxPRO) pre-filled syringes. For intramuscular injection.
Dose, frequency and maximum number of doses or period of time for administration or supply	0.5ml at birth intramuscularly in the anterolateral thigh. Note dose given. One by midwife, subsequent doses by Health Visitor or GP in accordance with Public Health agreed schedule of immunisations. See follow up.
Contra-indications/exclusion criteria	<ul style="list-style-type: none"> known hypersensitivity to any component of the medicine acute severe febrile illness (postpone) 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"> 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 maternity record
Medicine interactions and action that will be taken if a patient is taking a medicine that may interact	<ul style="list-style-type: none"> if there is a clinically significant drug interaction, consult with a doctor before administration or supply document consultation in baby record refer to current BNF for latest information on interactions

Hepatitis B vaccine Neonate

<p>Potential adverse reactions and side effects including actions to be taken if adverse drug reaction is suspected</p>	<ul style="list-style-type: none"> ▪ <i>it is well tolerated</i> ▪ <i>most common adverse reactions are soreness and redness at the injection site, fatigue</i> ▪ <i>other reactions include gastrointestinal symptoms (such as nausea vomiting, diarrhoea, abdominal pain), drowsiness, headache, dizziness, paraesthesia, fever, malaise, swelling at injection site, injection site reaction (such as induration), urticaria, pruritus, rash, malaise and an influenza-like syndrome, arthritis, arthralgia, myalgia, appetite loss, and abnormal liver function tests, lymphadenopathy</i> ▪ <i>serious very rare reactions such as Guillain-Barre syndrome and demyelinating disease</i> ▪ <i>apnoea in very premature infants (≤ 28 weeks of gestation)</i> ▪ <i>advise mother to contact health professional if side effects occur</i> ▪ <i>on labour</i> <i>Nil</i> ▪ <i>on the neonate</i> <i>Nil</i> ▪ <i>on breast feeding</i> <i>Nil</i> ▪ <i>if a serious adverse reaction is suspected please report to the MHRA Yellow Card Scheme http://yellowcard.mhra.gov.uk/</i>
<p>Overdose</p>	<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
<p>Action if patient declines</p>	<ul style="list-style-type: none"> ▪ refer to authorised prescriber or doctor ▪ document in maternity record
<p>Additional advice and information</p>	<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 ▪ give the manufacturer's patient information leaflet to the woman
<p>Patient monitoring arrangements during and after treatment and follow-up required</p>	<p>Refer baby to GP or Health Visitor for subsequent doses with the same brand of vaccine. Advise GP that serology testing is required 2-4 months after completion of the course.</p>
<p>Particular storage requirements</p>	<ul style="list-style-type: none"> ▪ Store at 2°C to 8°C (in a refrigerator). ▪ Do not freeze; discard if vaccine has been frozen.

Hepatitis B vaccine

Neonate

References

1. Summary of Product Characteristics
<http://www.medicines.org.uk> for Engerix B (revised 24.4.2017) and HBVAXPRO (revised 12.3.2019) 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

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 Accessed 27.12.2019