Prescribing Information

Please consult the Summary of Product Characteristics (SPC) before prescribing.

Engerix B Hepatitis B (rDNA) vaccine adsorbed (HBV). Suspension for injection in pre-filled syringe. **Composition:** 1 dose (0.5 ml) contains 10 µg Hepatitis B surface antigen; 1 dose (1 ml) contains 20 µg Hepatitis B surface antigen. **Uses:** Active immunisation against hepatitis B virus infection.

Dosage and administration: For i.m. use in the deltoid region in adults and children or in the anterolateral thigh in neonates, infants and young children. *Adults and children 16 years and above:* 20 µg (1 ml); *Neonates and children 15 years and under:* 10 µg (0.5 ml). Series of 3 injections required for primary immunisation: doses at 0, 1 and 6 months or accelerated schedule 0, 1 and 2 months with a fourth dose at 12 months. For more rapid protection in *patients 18 years and above*, exceptional schedule of 0, 7 and 21 days with a fourth dose at 12 months. Booster dose only if official vaccination programmes require. *Children from 11 up to and including 15 years*: 20 µg (1 ml) can be used, doses at 0, 6 months (protection may not occur until after the second dose). *Renal insufficiency including haemodialysis (patients up to 15 years of age):* 10 µg (0.5ml) *at* 0, 1, 2 and 12 months or 0, 1, 6 months*. Renal insufficiency including haemodialysis (patients 16 years and above):* 40 µg (2x 20 µg) at 0, 1, 2 and 6 months. *Known or presumed exposure to HBV:* The 0, 1, 2, 12 months schedule should be advised and may be adjusted to accommodate local immunisation practices.

Booster dose: in immunocompromised subjects (e.g. subjects with chronic renal failure, haemodialysis patients, HIV positive subjects), boosters should be administered to maintain anti-HBs antibody concentrations equal or higher than the accepted protective level of 10 IU/l. National recommendations on booster vaccination should be considered.

Contra-indications: Hypersensitivity to any component of the vaccine, severe febrile illness. **Precautions:** Syncope may occur before/after administration. Medical treatment/supervision to be available in case of anaphylaxis. Additional doses may be required for those who do not respond or have sub-optimal response. Potential risk of apnoea and need for respiratory monitoring in very premature infants (born ⩽ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. Vaccine should not be administered in the buttock or intradermally since this may result in a lower immune response. Exceptionally the vaccine may be administered subcutaneously in patients with thrombocytopenia or bleeding disorders. Engerix B should under no circumstances be administered intravascularly. Consider serological testing of subjects at risk of not achieving seroprotection following a complete course of Engerix B. **Interactions:** For information on the concomitant use of *Engerix B* with other vaccines please refer to the SPCs. Different injectable vaccines should always be administered at different injection sites. HBIg must be given at a separate injection site.

Pregnancy and lactation: Used during pregnancy only when clearly needed, and the possible advantages outweigh the possible risks for the foetus. The effect on breastfed infants of the administration of Engerix B to their mothers has not been evaluated, no contraindication in lactation has been established.

Adverse reactions: See SPC for full details. *Very common:* irritability, headache (paediatric use), pain and redness at injection site, fatigue. *Common*: drowsiness, headache (adult use), gastrointestinal symptoms, appetite loss, fever, malaise, swelling at injection site, injection site reaction. *Serious*: Thrombocytopenia, encephalitis, encephalopathy, convulsions, paralysis, neurological disorders, (including Guillain-Barré syndrome, optic neuritis and multiple sclerosis), apnoea in very premature infants (⩽28 weeks gestation), angioneurotic oedema, meningitis, vasculitis, anaphylaxis. **Legal category:** POM. **Presentation and basic NHS cost:** 1ml pre-filled syringe: 1, £12.99; 10, £129.92. 0.5ml pre-filled syringe: 1, £9.67. **MA number:** PL 10592/0166. **MA holder:** SmithKline Beecham Ltd. Trading as GlaxoSmithKline UK, 980 Great West Road, Brentford, Middlesex, TW8 9GS. **Further information is available from:** GSK Customer Contact Centre: customercontactuk@gsk.com; Freephone 0800 221 441. Engerix B is a registered trademark of the GlaxoSmithKline group of companies.

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Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk or search for MHRA Yellowcard in the Google Play or Apple App store. Adverse events should also be reported to GlaxoSmithKline 0800 221 441.