Prescribing Information - Refer to SPC before prescribing.

Engerix B. Hepatitis B (rDNA) vaccine adsorbed (HBV) **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 micrograms (1 ml); *Neonates and children 15 years and under:* 10 micrograms (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 micrograms (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 microgram (0.5ml) *at* 0, 1, 2 and 12 months or 0, 1, 6 months*; Renal insufficiency including haemodialysis (patients 16 years and above):* 40 micrograms (2x 20 micrograms) at 0, 1, 2 and 6 months. **Contra-indications:** Hypersensitivity to any component of the vaccine, severe febrile illness. **Precautions:** 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. **Pregnancy and lactation:** Used during pregnancy only when clearly needed, and the possible advantages outweigh the possible risks for the foetus. No contraindication in lactation has been established. **Adverse reactions**: See SPC for full details. *Common*: injection site reactions, fatigue, irritability, headaches, drowsiness, GI symptoms, appetite loss, fever, malaise. *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. 1ml vial. 1, £12.34; 10, £123.41. 0.5ml pre-filled syringe. 1, £9.67. **MA number** 10592/0165-6. **MA holder** SmithKline Beecham Ltd. Trading as: GlaxoSmithKline UK, Stockley Park West, Uxbridge, Middlesex, UB11 1BT. **Further information is available from:** Customer Contact Centre, GlaxoSmithKline, Stockley Park West, Uxbridge, Middlesex UB11 1BT; customercontactuk@gsk.com; Freephone 0800 221 441. *Engerix B* is a registered trademark of the GlaxoSmithKline group of companies. **Date of preparation:** July 2015 UK/VAC/0072/15

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441.