HBVAXPRO®
Hepatitis B vaccine (rDNA)

PRESCRIBING INFORMATION
Refer to Summary of Product Characteristics before prescribing

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to MSD, UK (Tel: 0208 1548000).
By clicking the above link you will leave the MSD website and be taken to the MHRA website.

PRESENTATION
HBvaxPRO 5 mcg: 0.5 ml suspension for injection in prefilled syringe contains 5 mcg of recombinant hepatitis B surface antigen.
HBvaxPRO 10 mcg: 1 ml suspension for injection in prefilled syringe contains 10 mcg of recombinant hepatitis B surface antigen.
HBvaxPRO 40 mcg: 1 ml suspension for injection in vial contains 40 mcg of recombinant hepatitis B surface antigen.

USES
For active immunisation against infection caused by all known sub-types of hepatitis B virus in subjects of all ages considered at risk of exposure to hepatitis B virus, or predialysis and dialysis adult patients.

DOSAGE AND ADMINISTRATION
Neonates and children (birth through 15 years of age): 0.5 ml of HBvaxPRO 5 mcg by intramuscular injection in the anterolateral thigh. The course of vaccination should include at least 3 injections according to primary immunisation schedules.
Neonates born to mothers who are hepatitis B virus carriers: first dose of HBvaxPRO 5 mcg within 7 days of birth given simultaneously with hepatitis B immunoglobulin at birth, at a separate injection site. Subsequent doses of vaccine according to local recommended vaccination schedule.
Adolescents and adults (16 years of age and over): 1 ml of HBvaxPRO 10 mcg by intramuscular injection in the deltoid.
Predialysis and dialysis adult patients: 1 ml of HBvaxPRO 40 mcg by intramuscular injection in the deltoid.
This vaccine should be administered intramuscularly. Do not inject intravascularly. Exceptionally, the vaccine may be administered subcutaneously in patients with thrombocytopoenia or bleeding disorders. Shake to obtain a slightly opaque white suspension before use.
A course should include at least 3 doses given at least 1 month apart. Common vaccination schedules (local guidelines should be consulted): HBvaxPRO 5 mcg and HBvaxPRO 10 mcg - 0, 1 and 6 months or at 0, 1, 2 and 12 months. In immunocompetent vaccines, the need for booster doses is not yet defined. However, some schedules recommend periodic booster doses. For immunocompromised vaccinees, consider a booster dose if the anti-HBs level is less than 10 IU/l. HBvaxPRO 40 mcg - 0, 1 and 6 months. A booster dose must be considered if the anti-HBs level is less than 10 IU/l.
Special dosage recommendations for known or presumed exposure to hepatitis B virus (e.g needlestick with contaminated needle): Hepatitis B immunoglobulin should be given as soon as possible after exposure (within 24 hours). The first dose of the vaccine should be given within 7 days of exposure and can be administered simultaneously with hepatitis B immunoglobulin but at a separate injection site. In the case of unvaccinated or incompletely vaccinated individuals, additional doses should be given as in the recommended immunisation schedule.

CONTRA-INDICATIONS
Hypersensitivity to any component of the vaccine. Postpone vaccination in presence of severe febrile illness or acute infection.

PRECAUTIONS
Ensure appropriate medical treatment is available in case of rare anaphylactic reactions. Vaccination may not be successful in patients who are in the incubation phase of hepatitis B infection at the time of vaccination. The vaccine will not prevent infection caused by other agents such as hepatitis A, hepatitis C and hepatitis E. Hypersensitivity reactions to formaldehyde and potassium thiocyanate used in the manufacturing process may occur. Use caution when vaccinating latex-sensitive individuals since the vial stopper contains dry natural latex rubber that may cause allergic reactions. *HBvaxPRO 5 mcg:* the potential risk of apnoea and the need for respiratory monitoring for 48-72 hours should be considered when administering

the primary immunisation series to very premature infants (born ≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed. *Pregnancy and breastfeeding:* exercise caution when prescribing.

SIDE EFFECTS

Refer to Summary of Product Characteristics for complete information on side-effects.

Common: transient soreness, erythema and induration at the injection site. *Very rare*ly, serious side effects have been reported although in many cases causality has not been established: thrombocytopenia, serum sickness, anaphylaxis, paralysis (Bell's palsy, facial paralysis), peripheral neuropathies (polyradiculoneuritis, Guillain Barré Syndrome), neuritis (including optical neuritis), myelitis (including transverse myelitis), encephalitis, demyelinating disease of the central nervous system, exacerbation of multiple sclerosis, multiple sclerosis, seizure, bronchospasm-like symptoms, erythema multiforme and angioedema.

PACKAGE QUANTITIES AND BASIC NHS COST

5 mcg: 1 prefilled syringe with two separate needles: £8.95;
10 mcg: 1 prefilled syringe with two separate needles: £12.20;
40 mcg: 1 vial: £27.60.

Marketing Authorisation number:

Great Britain:
5 mcg: PLGB 53095/0027
10 mcg: PLGB 53095/0025
40 mcg: PLGB 53095/0026

UK (Northern Ireland):
5 mcg: EU/1/01/183/024
10 mcg: EU/1/01/183/028
40 mcg: EU/1/01/183/015

Marketing Authorisation Holder:

GB: Merck Sharp & Dohme (UK) Ltd,
120 Moorgate, London EC2M 6UR, United Kingdom.
UK(NI): Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, The Netherlands

Legal category: POM

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