

Prescribing Information - Refer to SPC before prescribing.

Fendrix, hepatitis B (rDNA) vaccine (adjuvanted, adsorbed). **Uses:** Active immunisation against hepatitis B virus infection (HBV) caused by all known subtypes for patients with renal insufficiency (including pre-haemodialysis and haemodialysis patients) from the age of 15 years onwards. **Dosage and administration:** For i.m use in deltoid region. For primary immunisation: 4 separate 0,5ml doses (20 micrograms) at the following schedule: 0, 1, 2 and 6 months. Once initiated, course should be completed with Fendrix. It is not interchangeable with other commercially available HBV vaccines. Consider a booster dose according to national recommendations and guidelines. Fendrix can be used as a booster dose after a primary vaccination course with either Fendrix or any other commercial recombinant hepatitis B vaccine. **Contra-indications:** Hypersensitivity to any component of the vaccine or other hepatitis B vaccines. Acute severe febrile illness. **Precautions:** Appropriate medical treatment should be available in case of rare anaphylactic reaction after vaccination. Vaccination may not prevent hepatitis B infection in patients who are in the incubation period of hepatitis B infection at the time of vaccination. Avoid intramuscular administration into gluteal muscle due to suboptimal

response and in no circumstances administer intradermally or intravenously. **Interactions:** As no data are available for the concomitant administration of Fendrix with other vaccines, an interval of 2-3 weeks should be respected. **Pregnancy and lactation:** Balance risks and benefits.

Adverse reactions: See SPC for full details. *Common and very common:* headache, pain, fatigue, GI disorder, fever, injection site reactions. *Serious:* rigors, vertigo, paralysis, neuropathy, neuritis (including Guillain-Barré syndrome, optic neuritis and multiple sclerosis), encephalitis, encephalopathy, meningitis and convulsions. **Legal category:** POM. **Presentation and basic NHS cost:** 0.5ml pre-filled syringe. 1 unit, £38.10. **MA number:** EU/1/04/0299/001-2-3. **MA holder:** GlaxoSmithKline Biologicals s.a., Rue de l'Institut 89, B-1330 Rixensart, Belgium. For the UK, **further information** is available from GlaxoSmithKline Customer Contact Centre; customercontactuk@gsk.com; Freephone: 0800 221 441. For Ireland, please contact 1800 244 255. Fendrix is a registered trademark of the GlaxoSmithKline group of companies. **Date of preparation:** January 2021. **Ref:** PI-0506 (V3.0).

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