Fendrix (hepatitis B (rDNA) vaccine (adjuvanted, adsorbed)) PRESCRIBING INFORMATION

Please find below:

1. **PRESCRIBING INFORMATION for Great Britain (GB)**
2. **PRESCRIBING INFORMATION for Northern Ireland (*which is located below the GB Prescribing Information*)**

PRESCRIBING INFORMATION - Great Britain

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

Fendrix Suspension for Injection

Hepatitis B (rDNA) vaccine (adjuvanted, adsorbed). **Composition:** one dose (0.5ml) contains 20µg Hepatitis B surface antigen adjuvanted by AS04C (containing 50µg of 3-O-desacyl-4'-monophosphoryl lipid A (MPL)). **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 the deltoid region. For primary immunisation: 4 separate 0,5ml doses (20 µg) 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. Syncope (fainting) can occur following, or even before, any 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: There are no data from the use of Fendrix in pregnant women and no data during lactation. Balance risks and benefits.

Adverse reactions: See SPC for full details. *Very common and common*: headache, pain, fatigue, Gastrointestinal disorder, fever, injection site reactions. *Serious*: Anaphylaxis, 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: PLGB 19494/0267.

MA holder: GlaxoSmithKline UK Ltd, 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom. **Further information** is available from GlaxoSmithKline Customer Contact Centre; customercontactuk@gsk.com; Freephone: 0800 221 441. Fendrix is a registered trademark of the GlaxoSmithKline group of companies.

Date of preparation: November 2023.

Ref: PI-0506 (V5).

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.**

PRESCRIBING INFORMATION – Northern Ireland

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Legal category: POM. **Presentation and basic NHS cost:** 0.5ml pre-filled syringe. 1 unit, £38.10. **MA numbers**: EU/1/04/0299/001-2-3. **MA holder:** GlaxoSmithKline Biologicals s.a., Rue de l'Institut 89, B-1330 Rixensart, Belgium. **Further information** is available from GlaxoSmithKline Customer Contact Centre; customercontactuk@gsk.com; Freephone: 0800 221 441. Fendrix is a registered trademark of the GlaxoSmithKline group of companies.

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