PREHEVBRI® ▼ Hepatitis B vaccine (recombinant, adsorbed)

Prescribing Information: PreHevbri® 10 micrograms suspension for injection Hepatitis B vaccine (recombinant, adsorbed). **Presentation:** Each 1 mL dose contains 10 micrograms of Hepatitis B surface antigens (S [83%], pre-S2 [11%] and pre-S1 [6%]). Adsorbed on 500 micrograms of Al3+ as aluminium hydroxide, hydrated. Produced in Chinese Hamster Ovary cells by recombinant DNA technology. **Indications:** PreHevbri® is indicated for active immunisation against infection caused by all known subtypes of the hepatitis B virus in adults. It can be expected that hepatitis D will also be prevented by immunisation with PreHevbri® as hepatitis D (caused by the delta agent) does not occur in the absence of hepatitis B infection. **Dosage:** *Vaccination schedule:* The vaccination schedule consists of 3 doses (1 mL each) given according to the following schedule: first dose at an elected date; second dose 1 month after the first dose; third dose 6 months after the first dose. *Booster dose:* The need for a booster dose has not been established. No data are available. *Elderly population:* No dose adjustments are required in elderly persons aged 65 years and older. *Paediatric population:* The safety and efficacy of PreHevbri® in children have not yet been established. Limited data are available. **Administration:** PreHevbri® should be injected intramuscularly (IM) into the deltoid region. Do not inject intravascularly, subcutaneously or intradermally. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. History of severe allergic reaction, such as anaphylaxis, after a previous dose of any hepatitis B vaccine. **Warnings and Precautions:** Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine. Vaccination should be postponed in subjects suffering from acute severe febrile illness or acute infection. The presence of a minor infection and/or low-grade fever should not delay vaccination. Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia, and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury. PreHevbri® may not prevent hepatitis B infection in individuals who have an unrecognised hepatitis B infection at the time of vaccine administration. As with any vaccine, a protective immune response may not be elicited in all vaccinees. The vaccine will not prevent infection caused by other agents such as hepatitis A, hepatitis C, and hepatitis E, or other pathogens known to infect the liver. Thrombocytopenia and coagulation disorders: The vaccine should be given with caution in subjects receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these subjects. Immunodeficiency: Immunocompromised persons may have a diminished immune response to PreHevbri®. There are limited data available among immunocompromised population. Attention should be given to ensure that a protective antibody level is maintained as defined by national recommendations and guidelines. Patients with chronic liver disease or with HIV infection or hepatitis C carriers should not be precluded from vaccination against hepatitis B. The vaccine could be advised since hepatitis B infection can be severe in these patients - PreHevbri® should thus be considered on a case-by-case basis by the physician. Hepatitis B surface antigen (HBsAg) derived from hepatitis B vaccines has been transiently detected in blood samples following vaccination. Serum HBsAg detection may not have diagnostic value within 28 days after administration of PreHevbri®. Renal impairment: Pre-haemodialysis and haemodialysis patients are at risk

of exposure to hepatitis B virus and have a higher risk of becoming chronically infected. Attention should be given to ensure that a protective antibody level is achieved and maintained as defined by national recommendations and guidelines. Excipients with known effect:
Sodium: This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. is essentially 'sodium-free'. *Potassium*: This medicinal product contains less than 1 mmol potassium (39 mg) per dose, i.e. is essentially potassium-free'. **Interactions:** No interaction studies have been performed. There are no data on co-administration of PreHevbri® with other vaccines. The concomitant use of PreHevbri® with other vaccines is not recommended. When concomitant administration of PreHevbri® and immune globulin is required, they should be given with different syringes at separate injection sites. **Fertility, pregnancy, and lactation:** Pregnancy: There are no data from the use of the vaccine in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. Vaccination during pregnancy should only be performed if the benefit/risk ratio at individual level outweighs possible risks for the foetus. Breast-feeding: It is unknown whether PreHevbri® is excreted in human milk. A risk to the breastfed newborn/infant cannot be excluded. A decision must be made whether to discontinue breast-feeding or to abstain from PreHevbri® vaccination taking into account the benefit of breast-feeding for the child and the benefit of vaccination for the woman. Fertility: There are no data on fertility in humans from the use of PreHevbri®. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. **Ability to drive and use machines:** PreHevbri® has no or negligible influence on the ability to drive and use machines. However, some of the effects mentioned in side effects (e.g. fatigue, headache, dizziness) may temporarily affect the ability to drive or operate machines. **Side effects:** Very common side effects include: injection site pain, injection site tenderness, injection site pruritus, fatigue, headache and myalgia Common side effects include: diarrhoea, nausea/vomiting, abdominal pain, injection site swelling, injection site redness, injection site bruising, fever, dizziness, arthralgia, and rash. Uncommon side effects include: lymphadenopathy, urticaria, pruritus, flushing, and hot flush. The frequency and severity of solicited adverse events generally declined or remained similar with successive vaccinations. For a more detailed overview of side effects, please refer to Summary of Product Characteristics (SmPC). **Overdose:** No cases of overdose have been reported. **Legal category:** POM. **Packaging quantities:** 1 mL suspension in a single-dose glass vial, fitted with a rubber stopper and sealed with an aluminium seal with a plastic-coloured flip-off top. *Pack size:* 10 vials. **Basic cost:** £14.30 per dose. **Marketing Authorisation Holder:** VBI Vaccine B.V. Delflandlaan 1, Queen's Tower, No. 714, 1062EA Amsterdam, Netherlands. **Marketing Authorisation number(s):** PLGB 54272/0001.

For full prescribing information and details of other side effects please refer to the Summary of Product Characteristics which can be found at: www.medicines.org.uk/emc

Full prescribing information is available on request from: Medical Information, VALNEVA AUSTRIA GMBH, Campus Vienna Biocenter 3, 1030 Vienna, Vienna, Austria, FB-Nr: FN 389960 x / HG Wien. Telephone: +44 1506 446608. Email: medinfo@valneva.com

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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 the Valneva UK Ltd Medical Information department on Tel: +43 1 20620 1400 or via email: vaccinesafety@valneva.com