ALPROLIX® (eftrenonacog alfa) powder and solvent for solution for injection
PRESCRIBING INFORMATION (PI) FOR UNITED KINGDOM

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Composition: Contains human coagulation factor IX (rDNA), eftrenonacog alfa, respectively at 250 IU (50 IU/mL), 500 IU (100 IU/mL), 1000 IU (200 IU/mL), 2000 IU (400 IU/mL) or 3000 IU (600 IU/mL) after reconstitution. Also contains 0.3 mmol (6.4 mg) of sodium per vial.

Indications: Treatment and prophylaxis of bleeding in patients with haemophilia B (congenital factor IX deficiency). ALPROLIX® can be used for all age groups.

Dosage and Administration: Intravenous use. Treatment should be under the supervision of a physician experienced in the treatment of haemophilia. One International Unit (IU) of recombinant factor IX Fc activity is equivalent to that quantity of factor IX in one mL of normal human plasma. Rate of administration should not exceed 10 mL/min. Dose and duration of the substitution therapy depend on severity of factor IX deficiency, location, and extent of bleeding and on patient's clinical condition. Dose guide: *On-demand treatment*: For dosing in the treatment of bleeding episodes and surgery, refer to section 4.2 of the SmPC. Amount to be administered and frequency of administration should always be oriented to clinical effectiveness in the individual case. If a repeat dose is required to control the bleed, the prolonged half-life of ALPROLIX® should be considered (SmPC section 5.2). Time to peak activity is not expected to be delayed. *Prophylaxis*: For long term prophylaxis, the recommended dose is *either* 50 IU/kg once weekly, dose adjusted based on individual response, *or* 100 IU/kg once every 10 days, interval adjusted based on individual response. Patients who are well-controlled on a once every 10 days regimen, might be treated on an interval of 14 days or longer. Highest recommended dose for prophylaxis is 100 IU/kg. *Paediatric population*: Children <12 years old, more frequent, or higher doses may be required. Recommended starting dose is 50-60 IU/kg every 7 days. For adolescents (≥12 years old), dose recommendations are the same as for adults. Refer to the SmPC section 6.6 for instructions on reconstitution.

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

Special warnings and precautions for use: To improve traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. *Hypersensitivity*: Allergic type hypersensitivity reactions have been reported. Patients should be informed of the early signs of hypersensitivity reactions and be advised to discontinue use of the medicinal product immediately and contact their physician if such signs occur. In case of anaphylactic shock, standard medical treatment for shock should be implemented. *Inhibitors*: Patients treated with coagulation factor IX products should be monitored for development of inhibitors. Because of the risk of allergic reactions with factor IX products, the initial administrations of factor IX should, according to the treating physician's judgement, be performed under medical observation where proper medical care for allergic reactions could be provided. *Thromboembolism*: Patients with liver disease, postoperative patients, new-born infants, and patients at risk of thrombotic phenomena or coagulopathy should be monitored for early signs of thrombotic complications. *Cardiovascular events*: In patients with existing cardiovascular risk factors, substitution therapy with factor IX products may increase the cardiovascular risk. *Catheter-related complications*: If a central venous access device (CVAD) is required, risk of CVAD-related complications including local infections, bacteraemia and catheter site thrombosis should be considered. Listed warnings and precautions apply to adults and children. ALPROLIX® contains less than 1 mmol sodium (23 mg) per vial, essentially "sodium-free".

Interactions: No interactions of ALPROLIX® with other medicinal products have been reported. No interaction studies have been performed.

Fertility, pregnancy and lactation: No fertility data is available. Based on the rare occurrence of haemophilia B in women, experience regarding the use of factor IX during pregnancy and breast-feeding is not available. Therefore, factor IX should be used during pregnancy and breast-feeding only if clearly indicated.

Undesirable effects: Consult section 4.8 of the SmPC for the full list of undesirable effects.

Hypersensitivity or allergic reactions (which may include angioedema, burning and stinging at the infusion site, chills, flushing, generalised urticaria, headache, hives, hypotension, lethargy, nausea, restlessness, tachycardia, tightness of the chest, tingling, vomiting, wheezing) have been observed rarely and may in some cases progress to severe anaphylaxis (including shock). Nephrotic syndrome has been reported following attempted immune tolerance induction in haemophilia B patients with factor IX inhibitors and a history of allergic reaction. Patients with haemophilia B may develop neutralising antibodies (inhibitors) to factor IX. If such inhibitors occur, the condition will manifest itself as an insufficient clinical response. In such cases, it is recommended that a specialised haemophilia centre be contacted. Use of low purity factor IX products has been associated with instances of myocardial infarction, disseminated intravascular coagulation, venous

thrombosis, and pulmonary embolism. Use of high purity factor IX is rarely associated with thromboembolic complications. The adverse reactions at least possibly related to treatment are listed below.
Common (≥1/100 to <1/10): factor IX inhibition, hypersensitivity, headache, paraesthesia oral, obstructive uropathy, injection site erythema.
Legal Category: Prescription Only Medicine (POM).
Pack size: 1 glass vial of powder plus materials for reconstitution and infusion.
Price: NHS List Price: £1.20/IU
Marketing Authorisation Number(s): PLGB 30941/0003-0007
Marketing Authorisation Holder: Swedish Orphan Biovitrum AB (publ), SE-112 76 Stockholm, Sweden.
Further Information Available From: Swedish Orphan Biovitrum (UK) Ltd, Suite 2, Riverside 3, Granta Park, Great Abington, Cambridgeshire, CB21 6AD.
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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 Swedish Orphan Biovitrum Ltd at medical.info.uk@sobi.com or Telephone +44 (0) 800 111 4754.