ALPROLIX® ▼(eftrenonacog alfa) Abbreviated Prescribing Information

For further prescribing information, please refer to the ALPROLIX® Summary of Product Characteristics (SPC) **Composition:** The active substance is eftrenonacog alfa (recombinant coagulation factor IX, Fc fusion protein). Each vial of ALPROLIX® contains nominally 250, 500, 1000, 2000 or 3000 IU eftrenonacog alfa. The other ingredients are sucrose, L-histidine, mannitol, polysorbate 20, sodium hydroxide and hydrochloric acid. **Diluent:** Sodium chloride and water for injection. **Indications:** Indicated for the 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:** *On-demand treatment:* The calculation of the required dose of recombinant factor IX Fc is based on the empirical finding that 1 International Unit (IU) factor IX per kg body weight raises the plasma factor IX activity by 1% of normal activity (IU/dL). The required dose is determined using the following formula: Required units = body weight (kg) x desired factor IX rise (%) (IU/dL) x {reciprocal of observed recovery (IU/kg per IU/dL)}. Please refer to the SmPC for further information, including Table 1: Guide to ALPROLIX® dosing for treatment of bleeding episodes and surgery. *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. Some patients who are well-controlled on a once every 10 days regimen, might be treated on an interval of 14 days or longer. In some cases, especially in younger patients, shorter dosage intervals or higher doses may be necessary. The highest recommended dose for prophylaxis is 100 IU/kg. *Treatment monitoring:* Please refer to the SmPC for further information on treatment monitoring. *Elderly population:* There is limited experience in patient's ≥65 years old. *Previously untreated patients (PUPs):* The safety and efficacy of ALPROLIX® in PUPs have not yet been established. *Paediatric population:* For children <12 years old, more frequent or higher doses may be required and the recommended starting dose is 50-60 IU/kg every 7 days. For adolescents (≥12 years old), the dose recommendations are the same as for adults. Refer to the SmPC for instructions on reconstitution. **Contraindications:** Hypersensitivity to eftrenonacog alfa (recombinant human coagulation factor IX, and/or Fc domain) or to any of the excipients. **Precautions and Warnings**: Allergic type hypersensitivity reactions have been reported. Patients should be informed of the signs of hypersensitivity reactions. Patients should be advised to discontinue use of the product immediately and contact their physician if such signs occur. Implement standard treatment in cases of anaphylactic shock. All patients treated with coagulation factor IX products should be carefully monitored for the development of inhibitors. Patients with liver disease, post-operative patients, newborn infants, and patients at risk of thrombotic phenomena or coagulopathy should be monitored for early signs of thrombotic complications. In patients with existing cardiovascular risk factors, substitution therapy with factor IX may increase the cardiovascular risk. 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. Recording of batch number is recommended in order to maintain a link between the patient and the batch of the medicinal product. The listed warnings and precautions apply both to adults and children. ALPROLIX® contains 0.3 mmol (6.4 mg) sodium per vial. This should be taken into consideration by patients on a controlled sodium diet. **Interactions:** No interactions of human coagulation factor IX (rDNA) with other medicinal products have been reported. No interaction studies with ALPROLIX® have been performed. **Undesirable Effects:** Hypersensitivity or allergic reactions (swelling of the face, rash, hives, tightness of the chest and difficulty breathing, burning and stinging at the infusion site, chills, flushing, generalised urticaria, headache, hypotension, lethargy, nausea, restlessness, tachycardia, 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. In post-marketing experience, FIX inhibitor development and hypersensitivity (including anaphylaxis) have been observed. Patients with haemophilia B may develop neutralising antibodies (inhibitors) to factor IX. The use of low purity factor IX products has been associated with instances of myocardial infarction, disseminated intravascular coagulation, venous thrombosis and pulmonary embolism. The use of high purity factor IX is rarely associated with thromboembolic complications. Consult the SmPC for further information about adverse events. **Legal Category**: POM **Marketing Authorisation Nos.**: EU/5/16/1098/001-005. **Pack size:** 1 glass vial of powder plus materials for reconstitution and infusion. NHS List Price: £1.20/IU. Eire List Price: Available on request. **Marketing Authorisation Holder:** Swedish Orphan Biovitrum AB (publ), SE-112 76 Stockholm, Sweden. **Further information** is available from Swedish Orphan Biovitrum (UK) Ltd, Suite 2, Riverside 3, Granta Park, Great Abington, Cambridgeshire, CB21 6AD **Date of Revision**: June 2018 **Company Reference:** PP-4359

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. Adverse events should be reported. For reporting within the UK, forms and information can be found at www.mhra.gov.uk/yellowcard and for Republic of Ireland at www.hpra.ie. Adverse events should also be reported to Swedish Orphan Biovitrum Ltd at drugsafety@sobi.com

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