ALPROLIX® (eftrenonacog alfa), **powder and solvent for solution for injection**

Abbreviated Prescribing Information:
Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Composition: The active substance is eftrenonacog alfa (recombinant human coagulation factor IX, Fc fusion protein (rFIXFc)). 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 in all age groups for the treatment and prophylaxis of bleeding in patients with haemophilia B (congenital factor IX deficiency).

Dosage and Administration:
Intravenous use. Requires supervision by a physician experienced in haemophilia treatment.
On-demand treatment: 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 against bleeding, the recommended starting regimens are either 50 IU/kg once weekly, adjust dose based on individual response or 100 IU/kg once every 10 days, adjust interval 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. The highest recommended dose for prophylaxis is 100 IU/kg.
Elderly population: There is limited experience in patients ≥65 years.
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.

Contraindications: Hypersensitivity to eftrenonacog alfa or to any of the excipients.

Precautions and Warnings:
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.
Allergic type hypersensitivity reactions have been reported with ALPROLIX. Patients should be informed of the signs of hypersensitivity reactions and advised to discontinue use of the product immediately and contact their physician if such signs occur. Implement standard treatment in case 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. The listed warnings and precautions apply both to adults and children.
ALPROLIX contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially “sodium-free”. In case of treatment with multiple vials, the total sodium content should be taken into consideration

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

Undesirable Effects: Hypersensitivity or allergic reactions 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. 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.

Throughout the ALPROLIX clinical study program, one patient (1/33) (previously untreated) developed a low titre factor IX inhibitor associated with hypersensitivity. In post-marketing experience, factor IX inhibitor development and hypersensitivity (including anaphylaxis) have been observed.
Consult the SmPC for further information about adverse events.

Legal Category: Medicinal product subject to restricted medical prescription.

Marketing Authorisation Nos.: EU/1/16/1098/001-005.

Pack size: 1 glass vial of powder plus materials for reconstitution and infusion.

Marketing Authorisation Holder: Swedish Orphan Biovitrum AB (publ), SE-112 76 Stockholm, Sweden.

Date of SmPC revision: 11/02/2021

Date of preparation: March 2023
Company reference document number: PP-18282

Adverse events should be reported to Competent Authority
or to Swedish Orphan Biovitrum AB by email: drugsafety@sobi.com