ELOCTA® (efmoroctocog 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: Each vial contains respectively, nominally 250 IU, 500 IU, 750 IU, 1000 IU, 1500 IU, 2000 IU, 3000 IU and 4000 IU efmoroctocog alfa and approximately 83 IU/mL, 167 IU/mL, 250 IU/mL, 333 IU/mL, 500 IU/mL, 667 IU/mL, 1000 IU/mL and 1333 IU/mL respectively of recombinant efmoroctocog alfa after reconstitution. Also contains 0.6 mmol (or 14 mg) of sodium per vial.

Indication: Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency). ELOCTA® can be used for all age groups.

Dosage and Administration: Intravenous use. Treatment should be initiated under the supervision of a physician experienced in the treatment of haemophilia. One IU of recombinant factor VIII Fc activity is equivalent to that quantity of factor VIII in one mL of normal human plasma. ELOCTA® should be injected intravenously over several minutes. The rate of administration should be determined by the patient's comfort level and should not exceed 10 mL/min The dose and duration of the substitution therapy depend on the severity of the factor VIII deficiency, on the location and extent of the bleeding and on the patient's clinical condition. Dose guide: On demand: The calculation of the required dose of recombinant factor VIII Fc is based on the empirical finding that 1 IU factor VIII per kg body weight raises the plasma factor VIII activity by 2 IU/dL. The required dose is determined using the following formula: Required units = body weight (kg) × desired factor VIII rise (%) (IU/dL) × 0.5 (IU/kg per IU/dL). The amount to be administered and the frequency of administration should always be oriented to the clinical effectiveness in the individual case. For ELOCTA® dosing in the treatment of bleeding episodes and surgery, refer to section 4.2 of the SmPC. Prophylaxis: For long term prophylaxis, the recommended dose is 50 IU of factor VIII per kg body weight at intervals of 3 to 5 days. The dose may be adjusted based on patient response in the range of 25 to 65 IU/kg (consult SmPC sections 5.1 and 5.2). In some cases, especially in younger patients, shorter dosage intervals or higher doses may be necessary. Elderly: There is limited experience in patients ≥65 years. Paediatric population: For children <12 years old, more frequent, or higher doses may be required. 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: Hypersensitivity: Allergic type hypersensitivity reactions are possible with ELOCTA®. Patients should be informed of the signs of hypersensitivity reactions and be advised to discontinue use of the medicinal product immediately and contact their physician. In case of shock, standard medical treatment for shock should be implemented. Inhibitors: The formation of neutralising antibodies (inhibitors) to factor VIII is a known complication in the management of individuals with haemophilia A. Patients treated with coagulation factor VIII products should be carefully monitored for the development of inhibitors by appropriate clinical observations and laboratory tests. If the expected factor VIII activity plasma levels are not attained, or if bleeding is not controlled with an appropriate dose, testing for factor VIII inhibitor presence should be performed. In patients with high levels of inhibitor, factor VIII therapy may not be effective and other therapeutic options should be considered. Cardiovascular events: In patients with existing cardiovascular risk factors, substitution therapy with factor VIII 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. Traceability: In order to improve traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. Paediatric population: The listed warnings and precautions apply to adults, children, and adolescents. Excipient related considerations: ELOCTA® contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

Interactions: No interactions of human coagulation factor VIII (rDNA) with other medicinal products have been reported. No interaction studies have been performed.

Fertility, pregnancy and lactation: Based on the rare occurrence of haemophilia A in women, experience regarding the use of factor VIII during pregnancy and breast-feeding is not available. Therefore, factor VIII 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). Development of neutralising antibodies (inhibitors) may occur in patients with haemophilia A treated with factor VIII, including with ELOCTA®. 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. The adverse reactions reported in clinical trials include the following:

Very common (≥1/10) in previously untreated patients (PUPs): FVIII inhibition

Common (≥1/100 to <1/10) in previously untreated patients (PUPs): papular rash, device related thrombosis.

Please consult the SmPC in relation to other adverse reactions.

Paediatric population: No age-specific differences in adverse reactions were observed between paediatric and adult subjects. Frequency, type and severity of adverse reactions in children are expected to be the same as in adults.

Legal Category: Prescription Only Medicine (POM).

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

Price: NHS List Price: £0.85/IU.

MA Numbers: PLGB 30941/0008-0015

MA Holder: Swedish Orphan Biovitrum AB (publ)

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