ELOCTA® ▼ (efmoroctocog alfa)

Abbreviated Prescribing Information

For further prescribing information, please refer to the ELOCTA® Summary of Product Characteristics (SPC)

ELOCTA®: Contains efmoroctocog alfa, respectively at 250 IU (83 IU/mL); 500 IU (167 IU/mL); 750IU (250IU/mL); 1000 IU (333 IU/mL); 1500 IU (500 IU/mL); 2000 IU (667 IU/mL); 3000 IU (1000 IU/mL). Also contains 14 mg equivalent to 0.6 mmol 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. Requires supervision by a physician experienced in haemophilia treatment. One IU of efmoroctocog alfa is equivalent to one IU of factor VIII in a milliliter of normal human plasma. The rate of administration should not exceed 10 mL/min.
Treatment dose and duration depend on the severity of factor VIII deficiency, the location and extent of bleeding, and the patient's clinical condition. Dose guide: *Prophylaxis:* The recommended dose is 50IU/kg every 3 to 5 days. The dose may be adjusted based on patient response in the range of 25 to 65 IU/kg. In some cases, especially in younger patients, shorter dosage intervals or higher doses may be necessary.
On demand: For ELOCTA® dosing in the treatment of bleeding episodes and surgery, refer to the SmPC. The amount to be administered and the frequency of administration should always be oriented to the clinical effectiveness in the individual case (see section 5.2 in the SmPC). The time to peak activity is not expected to be delayed.

Contraindications: Hypersensitivity to efmoroctocog alfa or other ingredients.

Warning and Precautions: Allergic hypersensitivity reactions are possible. Ensure patients are familiar with the signs of hypersensitivity. Discontinue use if reactions occur. Carefully monitor for the development of neutralising antibodies (inhibitors) to factor VIII. In cases of high inhibitor levels, consider other therapeutic options. May increase cardiovascular risk in patients with existing cardiovascular risk factors. Consider risks associated with use of central venous access device complications, if appropriate. It is recommended that the name and batch number of the product are recorded. Contains sodium. **Interactions:** None known. However, in the absence of compatibility studies, do not mix this medicine with other medicinal products.

Undesirable Effects: Hypersensitivity or allergic reactions. Very common (Previously Untreated Patients): FVIII inhibition. For a full list of side effects, refer to the SmPC.

Legal Category: Medicinal product subject to restricted medical prescription. **Pack size:** 1 unit (glass vial of powder with 3 mL solvent in a glass pre-filled syringe plus materials for reconstitution and infusion), NHS List Price: £ 0.85/IU. **MA Numbers:** EU/1/15/1046/001 –007. **MA Holder:** Swedish Orphan Biovitrum AB (publ), SE-112 76 Stockholm, Sweden. **Local representative:** Sobi Ltd Suite 2, Riverside 3, Granta Park, Great Abington, Cambridgeshire, CB21 6AD. Additional information and full Prescribing Information is available on request from the local representative.
Date of Preparation: May 2020 **Company Reference:** PP-8277

▼ 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. Forms and information can be found at www.mhra.gov.uk/yellowcard . Adverse events should also be reported to Swedish Orphan Biovitrum Ltd at drugsafety@sobi.com

SWEDISH ORPHAN BIOVITRUM LTD
Suite 2, Riverside 3,
Granta Park,
Great Abington,
Cambridgeshire,
CB21 6AD, UK