ALTUVOCT® ▼(Efanesoctocog alfa) - Prescribing Information

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

ALTUVOCT®: Contains human coagulation factor VIII efanesoctocog alfa, respectively at 250, 500, 750, 1000, 2000, 3000 or 4000 IU after reconstitution. The other ingredients are sucrose, calcium chloride dihydrate, histidine, arginine hydrochloride and polysorbate 80.

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

Dosage and Administration: Intravenous use. Requires supervision by a physician experienced in haemophilia treatment. The entire ALTUVOCT® dose should be injected intravenously over 1 to 10 minutes, based on the patient's comfort level. Refer to the SPC section 6.6 for instructions on reconstitution. *On-demand treatment:* The dose and duration of the treatment depend on the severity of factor VIII deficiency, location, and extent of the bleeding and on the patient's clinical condition. Please refer to the SmPC (Section 4.2: Table 1) for further information about treatment of bleeding episodes and surgery. *Prophylaxis:* The recommended dosing for routine prophylaxis for adults and children is 50 IU/kg of ALTUVOCT® administered once weekly. *Elderly population:* There is limited experience in patients ≥ 65 years. The dosing recommendations are the same as for patients < 65 years. *Paediatric population*: The dosing recommendations are the same as for adults. Refer to the SPC section 6.6 for instructions on reconstitution.

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

Warnings and Precautions: *Traceability*: 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 are possible with ALTUVOCT®. 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. *Inhibitors*: All patients treated with coagulation factor VIII products should be carefully monitored for the development of inhibitors. *In vitro* determination of factor VIII activity is significantly affected by the type of assay used. Please refer to SmPC for further information. *Monitoring Laboratory tests*: If the chromogenic assay or the one-stage clotting assay with Actin-FS reagent are used, divide the result by 2.5 to approximate the patient's factor VIII activity level. This conversion factor only represents an estimate. *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. *Paediatric population*: The listed warnings and precautions apply both to adults and children.

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

Undesirable Effects: Consult SmPC for full details. Hypersensitivity or allergic reactions have been observed rarely and may in some cases progress to severe anaphylaxis (including shock). Patients with haemophilia A may develop neutralising antibodies (inhibitors) to factor VIII. The following frequencies of adverse reactions for ALTUVOCT® have been reported. Very common (>=1/10) effects: headache (Including Migraine), arthralgia; Common (>=1/100 to <1/10) effects: vomiting, eczema, rash (including rash maculo papular), urticaria (including urticaria papular), pain in extremity, back pain, pyrexia; Uncommon effects (≥1/1 000 to <1/100): injection site reaction (including injection site haematoma and injection site dermatitis).

Legal Category: Prescription only medication (POM). **Pack size**: 1 glass vial of powder plus materials for reconstitution and infusion. **Price**: Eire List Price available on request. **MA Numbers:** EU/1/24/1824/001-007 **MA Holder**: Swedish Orphan Biovitrum AB (publ), SE-112 76 Stockholm, Sweden. **Local Representative**: Swedish Orphan Biovitrum (UK) 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**: October 2024 **Company Reference**: PP-25125

▼ 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. Reporting forms and information can be found at www.hpra.ie. Adverse events should also be reported to Swedish Orphan Biovitrum Ltd at medical.info.uk@sobi.com or Telephone +44 (0) 800 111 4754

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