▼ ALTUVOCT® (Efanesoctocog alfa) powder and solvent for solution for injection

PRESCRIBING INFORMATION (PI) FOR REPUBLIC OF IRELAND

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Contains human coagulation factor VIII efanesoctocog alfa, respectively at 250, 500, 750, 1000, 2000, 3000 or 4000IU 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. After proper training in the correct injection technique (see section 6.6 of the SmPC and the package leaflet), a patient may self-inject ALTUVOCT®, or the patient's caregiver may administer it, if their physician determines that it is appropriate. The entire ALTUVOCT® dose should be injected intravenously over 1 to 10 minutes, based on the patient's comfort level. For instructions on dilution of the medicinal product before administration, see section 6.6 of the SmPC. 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 50IU/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 section 6.6 of the SmPC for instructions on reconstitution.

Contraindications: Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 of the SmPC.

Special 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, including anaphylactic reactions have been observed with ALTUVOCT®. If symptoms of hypersensitivity occur, patients should be advised to discontinue use of the medicinal product immediately and contact their physician. Patients should be informed of the early signs of hypersensitivity reactions including hives, generalised urticaria, itching, nausea, vomiting, tightness of the chest, wheezing, hypotension, and anaphylaxis. In case of shock, standard medical treatment for shock should be implemented. 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 section 4.4 of the 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.

Fertility, pregnancy and lactation: Animal reproduction studies have not been conducted with factor VIII. 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 lactation only if clearly indicated.

Undesirable Effects: Consult section 4.8 of the SmPC for full details of undesirable effects. Hypersensitivity or allergic reactions (which may include angioedema, burning and stinging at the injection 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). Patients with haemophilia A may develop neutralising antibodies (inhibitors) to factor VIII. The following frequencies of adverse reactions for ALTUVOCT® have been reported. If such inhibitors occur, the condition may manifest itself as an insufficient clinical response. In such cases, it is recommended that a specialised haemophilia centre be contacted.

Very common (≥1/10): Headache (including migraine), arthralgia, Factor VIII inhibition in Previously Untreated Patients (PUPs) (frequency is based on studies with other Factor VIII products which included PUPs with severe haemophilia A.

Common (>=1/100 to <1/10): Vomiting, eczema, rash (including rash maculo papular), urticaria (including urticaria papular), pain in extremity, back pain, pyrexia.
Uncommon (≥1/1000 to <1/100): Injection site reaction (including injection site haematoma and injection site dermatitis), Factor VIII inhibition in Previously Treated Patients (PTPs) (frequency is based on studies with other Factor VIII products which included PTPs with severe haemophilia A.
Unknown frequency: Hypersensitivity, anaphylactic reaction (reported in post-marketing setting).
Legal Category: Prescription only medication (POM).
Marketing Authorisation Numbers: EU/1/24/1824/001-007
Pack size: 1 glass vial of powder plus materials for reconstitution and infusion.
Price: Eire List Price available on request.
Marketing Authorisation Holder: Swedish Orphan Biovitrum AB (publ), SE-112 76 Stockholm, Sweden.
Further information available from: Swedish Orphan Biovitrum (UK) Ltd, Suite 2, Riverside 3, Granta Park, Great Abington, Cambridgeshire, CB21 6AD.
Date of Preparation: May 2026
Company Reference: PP-33732

▼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.