ELOCTA 250 IU, ELOCTA 500 IU, ELOCTA 750 IU, ELOCTA 1000 IU, ELOCTA 1500 IU, ELOCTA 2000 IU, ELOCTA 3000 IU and ELOCTA 4000 IU powder and solvent for solution for injection

Abbreviated Prescribing Information: Please refer to the Summary of Product Characteristics (SmPC September 2020) before prescribing.

Composition: The active substance is efmoroctocog alfa (recombinant coagulation factor VIII, Fc fusion protein). Each vial of ELOCTA contains nominally 250, 500, 750, 1000, 1500, 2000, 3000 or 4000 IU efmoroctocog alfa. The other ingredients are sucrose, sodium chloride, histidine, calcium chloride dehydrate, polysorbate 20, sodium hydroxide and hydrochloric acid. **Indications:** Indicated in all age groups for the treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency). **Dosage and Administration:** Intravenous use. Treatment should be initiated under the supervision of a physician experienced in the treatment of haemophilia. For instructions on for preparation and administration refer to the SmPC. *On-demand treatment:* The required dose is determined using the following formula: **Required units = body weight (kg) x desired factor VIII rise (%) (IU/dL) x 0.5 (IU/kg per IU/dL).** Please refer to the SmPC for further information, including Table 1: Guide to ELOCTA dosing for treatment of bleeding episodes and surgery. *Prophylaxis:* For long-term prophylaxis, the recommended dose is 50 IU/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. *Treatment monitoring:* Please refer to the SmPC for further information on treatment monitoring. *Elderly population:* Limited experience in patients ≥ 65 years of age. *Paediatric population:* For children < 12 years of age, more frequent or higher doses may be required. For adolescents ≥ 12 years of age, the dose recommendations are the same as for adults. There is data for ELOCTA® in all ages groups, including in Previously Untreated Patients. **Contraindications:** Hypersensitivity to efmoroctocog alfa (recombinant human coagulation factor VIII, and/or Fc domain) or to any of the excipients. **Precautions and Warnings:** Allergic type hypersensitivity reactions are possible. Patients should be informed of the signs of hypersensitivity reactions, advised to discontinue use of the product immediately and contact their physician if such signs should occur. All patients treated with coagulation factor VIII products should be carefully monitored for the development of inhibitors. In patients with existing cardiovascular risk factors, substitution therapy with FVIII 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. Recording of batch number is recommended in order to maintain a link between the patient and the batch of the medicinal product. The listed warnings and precautions apply both to adults and children. ELOCTA contains less than 1mmol sodium (23mg) 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 with ELOCTA have been performed. **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. Inhibitor development is very common in patients that have not been previously treated with factor VIII. Papular rash and device-related thrombosis are common in previously untreated patients. Consult the SmPC for further information about adverse events.

Legal Category: Medicinal product subject to restricted medical prescription. **Marketing Authorisation Nos.:** EU/1/15/1046/001 – 008. **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. **Document number:** PP-18281
Date of Preparation: March 2023.

Prescribing information may differ between countries.

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