ALTUVIIIO®

Antihemophilic Factor (Recombinant),
Fc-VWF-XTEN Fusion Protein

THE FIRST AND ONLY HEMOPHILIA A TREATMENT THAT DELIVERS

MORE DAYS NEAR NORMAL

FACTOR VIII ACTIVITY LEVELS

Once-weekly ALTUVIIIO is a first-in-class, high-sustained Factor VIII replacement therapy that provides normal to near-normal levels (>40%) for most of the week in adults.[1]

Presentation: ALTUVIIIO (efanesoctocog alfa) powder and solvent for solution for injection. **Indications:** For use in adults and children with hemophilia A for routine prophylaxis to reduce frequency of bleeding episodes, or on-demand treatment and control of bleeding episodes, or perioperative management of bleeding. **Dosage and Administration:** For intravenous use after reconstitution only. Routine Prophylaxis: 50 IU/kg administered once weekly. On-demand Treatment and Control of Bleeding Episodes: Single dose of 50IU/kg. For minor and moderate bleeding episodes occurring within 2 to 3 days after a prophylactic dose, a lower dose of 30 IU/kg dose may be used. Additional doses of 30 or 50 IU/kg every 2 to 3 days may be considered. For major bleeding episodes, additional doses of 30 or 50 IU/kg every 2 to 3 days can be considered. Recommend to allow at least 72 hours between the last 50 IU/kg dose for treatment of a bleed and resuming prophylaxis dosing. Prophylaxis can be continued as usual thereafter. Perioperative Management: Single dose of 50IU/kg. For minor surgery, an additional dose of 30 or 50 IU/kg after 2 to 3 days may be considered. For major surgery, additional doses of 30 or 50 IU/kg every 2 to 3 days may be administered as clinically needed. *For full dosage information, please refer to the full prescribing information.* **Contraindications:** Severe hypersensitivity reactions, including anaphylaxis, to the product or its excipients. **Precautions:** Inform patients of signs of hypersensitivity reactions that may progress to anaphylaxis. Advise patients to discontinue use of ALTUVIIIO if hypersensitivity symptoms occur and contact a physician and/or seek immediate emergency care. Monitor all patients for development of Factor VIII inhibitors by appropriate clinical observations and laboratory tests. Perform appropriate testing if the patient's plasma Factor VIII level fails to increase as expected or if bleeding is not controlled after ALTUVIIIO administration. Recommend to use a validated one-stage clotting assay if assessment of plasma Factor VIII activity is needed. In patients with existing cardiovascular risk factors, substitution therapy with Factor VIII may increase cardiovascular risk. If a central venous access device (CVAD) is required, risk of CVAD-related complications should be considered. **Drug Interactions:** None. **Pregnancy and lactation:** Not known whether ALTUVIIIO can affect reproductive capacity or cause fetal harm when given to pregnant women. Consider the developmental and health benefits of breastfeeding along with the mother's clinical need for ALTUVIIIO and any potential adverse effects on the breastfed infant from ALTUVIIIO or from the underlying maternal condition. **Undesirable Effects:** Headache, arthralgia, pain in extremity, back pain, pyrexia, vomiting. *For other undesirable effects, please refer to the full prescribing information.* **Preparation:** 1 x 500IU or 3000IU ALTUVIIIO vial, with 1 pre-filled syringe with solvent and 1 vial adapter. **Legal Classification:** Part 1, Schedule 1 & Schedule 3 Poison

Full prescribing information is available upon request.

Reference: 1. Drygalski AV, et al. N Engl J Med. 2023;388(4):310-318.

API-HK-ATV-24.10

MAT-HK-2500524-1.0-10/2025

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