ALTUVIIIO™

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

DOSING GUIDE

SIMPLE DOSING

ALTUVIIIO can meet the needs of your hemophilia A patients across treatment scenarios.[1]

Your guide for dosing once-weekly prophylaxis, on-demand, and perioperative use.[1]

INDICATION

ALTUVIIIO™ [antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl] is a von Willebrand Factor (VWF) independent recombinant DNA-derived, Factor VIII concentrate indicated for use in adults and children with hemophilia A (congenital factor VIII deficiency) for:

- Routine prophylaxis to reduce the frequency of bleeding episodes
- On-demand treatment & control of bleeding episodes
- Perioperative management of bleeding

Limitation of Use

ALTUVIIIO is not indicated for the treatment of von Willebrand disease.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ALTUVIIIO is contraindicated in patients who have had severe hypersensitivity reactions, including anaphylaxis, to the product or its excipients.

Please see full Prescribing Information and Important Safety Information throughout.

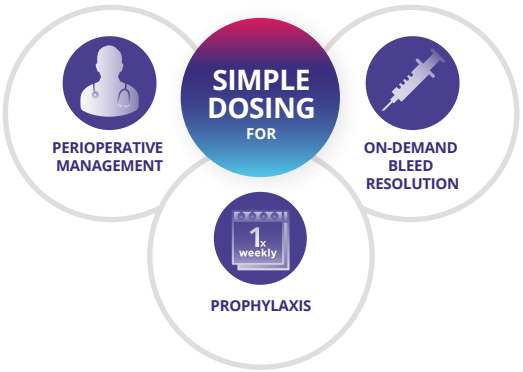
ALTUVIIIO: SIMPLICITY IN DOSING

PROPHYLAXIS[1]

For routine prophylaxis in adults, adolescents, and children

50 IU/kg **ADMINISTERED ONCE WEEKLY**

Dosing adjustment is not required for pediatric patients.



ON-DEMAND BLEED RESOLUTION[1]

Recommended dose for bleed resolution

In the on-demand arm of the XTEND-1 pivotal trial, 96.7% (350/362) of breakthrough bleeds were resolved with a single infusion of ALTUVIIIO.[1,2]

Type of Bleeding	Recommended Dose	Additional Information
Minor and Moderate*	Single dose of 50 IU/kg	• For minor/moderate bleeding episodes within 2-3 days after prophylactic dose, 30 IU/kg dose may be used • Additional doses of 30 or 50 IU/kg every 2-3 days can be considered
Major†	Single dose of 50 IU/kg	• Additional doses of 30 or 50 IU/kg every 2-3 days can be considered

For resumption of prophylaxis (if applicable) after treatment of a bleed, it is recommended to allow an interval of at least 72 hours between the last 50 IU/kg dose for treatment of a bleed and resuming prophylaxis dosing. Thereafter, prophylaxis can be continued as usual on the patient's regular schedule.

Study design: 159 previously treated patients (≥12 years old) were enrolled in the Phase 3 XTEND-1 study. Patients in Arm A switched from prior prophylaxis therapy to ALTUVIIIO prophylaxis, and patients in Arm B switched from prior on-demand therapy to ALTUVIIIO on-demand and finally ALTUVIIIO prophylaxis. The efficacy of ALTUVIIIO compared with previous Factor VIII therapy was also evaluated in patients who had participated in a prospective observational study (OBS16221) prior to enrollment in the XTEND-1 study (n=78).[1,2]

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS

- Allergic-type hypersensitivity reactions, including anaphylaxis, may occur with ALTUVIIIO. Allergic-type hypersensitivity reactions were not reported in the clinical trials. Advise patients to discontinue use of ALTUVIIIO if hypersensitivity symptoms occur and contact a physician and/or seek immediate emergency care.

*Includes uncomplicated joint bleeds, minor muscular bleeds, mucosal, or subcutaneous bleeds.
†Includes intracranial, retroperitoneal, iliopsoas and neck bleeds, muscle bleeds with compartment syndrome, and bleeds associated with a significant decrease in the hemoglobin level.

IU=international unit.

Please see full Prescribing Information and Important Safety Information throughout.

PERIOPERATIVE MANAGEMENT[1]

Recommended dose for protection during medical procedures

Type of Surgery	Preoperative Dose	Postoperative Dose
Minor	Single dose of 50 IU/kg	• An additional postoperative dose of 30 or 50 IU/kg after 2-3 days may be considered
Major[‡]	Single dose of 50 IU/kg	• Additional postoperative doses of 30 or 50 IU/kg every 2-3 days may be administered as clinically needed

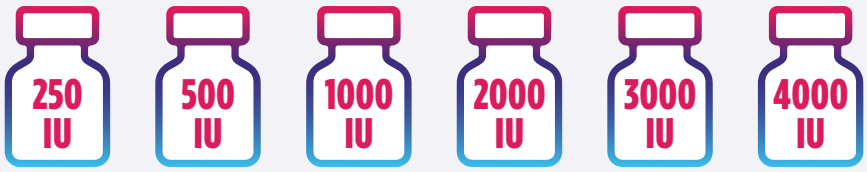
[‡]Includes intracranial, intra-abdominal, joint-replacement surgery, or complicated dental procedures.

For the dose of 50 IU/kg, the expected in vivo peak increase in Factor VIII level expressed as IU/dL (or % of normal) is estimated using the following formula:

Estimated increment of Factor VIII (IU/dL or % of normal) = 50 IU/kg × 2 (IU/dL per IU/kg)[1]

To achieve a specific target Factor VIII activity level, use the following formula: Dosage (IU) = Body Weight (kg) x Desired Factor VIII Increase (IU/dL or % normal) x 0.5 (IU/kg per IU/dL).

6 **vial sizes to optimize administration[1§]**



[§]Vials shown are only representational.

Quickly find your patients' doses with the dosing calculator.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

- Formation of neutralizing antibodies (inhibitors) to Factor VIII are possible following administration of ALTUVIIIO. Neutralizing antibodies were not reported in the clinical trials. Monitor all patients for the development of Factor VIII inhibitors by appropriate clinical observations and laboratory tests.

Please see full Prescribing Information and Important Safety Information throughout.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

- If assessment of plasma Factor VIII activity is needed, it is recommended to use a validated one-stage clotting assay. The ALTUVIIIO Factor VIII activity level is overestimated by the chromogenic assay and a specific ellagic acid-based aPTT reagent in one-stage clotting assay by approximately 2.5-fold. If these assays are used, divide the result by 2.5 to approximate the patient's ALTUVIIIO Factor VIII activity level.

ADVERSE REACTIONS

The most common adverse reactions (>10% of subjects) reported in clinical trials were headache and arthralgia**.**

Reconstitution and administration are straightforward.
Watch this **patient video** on how to infuse**.**

Please see full Prescribing Information and Important Safety Information throughout.

References: 1. ALTUVIIIO Prescribing Information. Bioverativ Therapeutics Inc. Waltham, MA. **2.** von Drygalski A, et al. *N Engl J Med.* 2023;388:310-318.

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