

ALTUVIIIIO[®]

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

DOSING GUIDE

SIMPLE DOSING

ALTUVIIIIO 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

ALTUVIIIIO[®] [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

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ALTUVIIIIO 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.

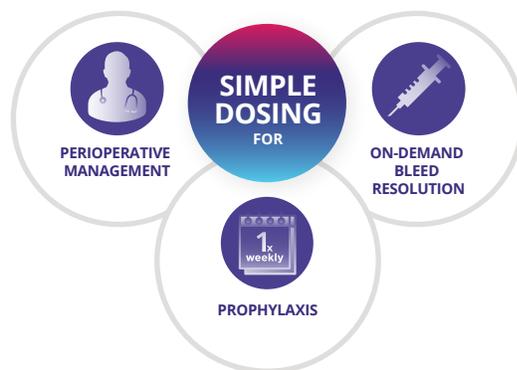
ALTUVIII[®]: SIMPLICITY IN DOSING

PROPHYLAXIS¹

For routine prophylaxis in adults, adolescents, and children*

50 IU/kg ADMINISTERED ONCE WEEKLY

Perform infusion slowly over 1 to 10 minutes, based on the patient's comfort level.



ON-DEMAND BLEED RESOLUTION¹

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 ALTUVIII[®].¹

Type of Bleeding	Recommended Dose	Additional Information
Minor and Moderate [‡]	Single dose of 50 IU/kg	<ul style="list-style-type: none">For minor/moderate bleeding episodes within 2-3 days after prophylactic dose, 30 IU/kg dose may be usedAdditional doses of 30 or 50 IU/kg every 2-3 days can be considered
Major [‡]	Single dose of 50 IU/kg	<ul style="list-style-type: none">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.¹

Study design: 159 previously treated patients (≥ 12 years) were enrolled in the Phase 3 XTEND-1 study. Patients in Arm A switched from prior prophylaxis therapy to ALTUVIII[®] prophylaxis, and patients in Arm B switched from prior on-demand therapy to ALTUVIII[®] on-demand and finally ALTUVIII[®] prophylaxis. The efficacy of ALTUVIII[®] 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).¹⁻³

*Dosing adjustment is not required for pediatric patients.¹

[‡]Includes uncomplicated joint bleeds, minor muscular bleeds, mucosal, or subcutaneous bleeds.¹

[‡]Includes intracranial, retroperitoneal, iliopsoas and neck bleeds, muscle bleeds with compartment syndrome, and bleeds associated with a significant decrease in the hemoglobin level.¹

IU=international unit.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS

- Allergic-type hypersensitivity reactions, including anaphylaxis, have occurred with ALTUVIII[®]. Discontinue use of ALTUVIII[®] if hypersensitivity reaction occurs and manage symptoms as appropriate.

Please see full [Prescribing Information](#) and [Important Safety Information](#) throughout.

PERIOPERATIVE MANAGEMENT¹

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.¹

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 administration¹



¹Vials 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 ALTUVIII[®]O. 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 ALTUVIIIIO 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 ALTUVIIIIO 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.** ALTUVIIIIO Prescribing Information. Bioverativ Therapeutics Inc. Waltham, MA. **2.** von Drygalski A, et al. *N Engl J Med.* 2023;388(4):310-318. **3.** Data on file, March 2022.

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