

FACTOR VIII (RECOMBINANT) LONG ACTING

Antihemophilic Factor (Recombinant BDD) Fc Fusion Protein; Eloctate®

CLASSIFICATION

- Coagulation factor.

INDICATIONS

- Eloctate® is a recombinant anti-hemophilic factor indicated in adults and children with hemophilia A (congenital factor VIII deficiency) for:
 - Routine prophylactic treatment to prevent or reduce the frequency of bleeding episodes
 - Control and prevention of bleeding episodes
 - Perioperative management (surgical prophylaxis)

ADMINISTRATION

- Each single-use vial of lyophilized powder contains: nominally 250, 500, 750, 1000, 1500, 2000 or 3000 International Units (IU) of Antihemophilic Factor (Recombinant BDD), Fc Fusion Protein. When diluted as directed, the reconstituted product contains 83, 167, 250, 333, 500, 667 and 1000 IU/mL respectively. Each vial has the actual factor VIII potency in International Units (IU) stated on the label.
- Reconstitute each vial using the vial adapter reconstitution device and the prefilled 3 mL diluent syringe provided in the package. Gently rotate the vial until all of the powder is dissolved. Draw the solution back into the syringe. The solution should be clear to slightly opalescent and colorless.
- IV direct: physician or RHCP; over several minutes using the infusion set provided

POTENTIAL ADMINISTRATION HAZARDS

- Hypersensitivity: fever, chills, facial swelling, flushing, rash, hives, hypotension, wheezing, anaphylaxis (rare).
- Arthralgia, malaise, myalgia, headache and rash.
- Development of activity-neutralizing antibodies (factor VIII inhibitors).

DOSAGE

- Refer to the Eloctate® product monograph.

COMPATIBILITY, STABILITY

- Store unopened vials at 2 to 8°C. The product may be stored at 15-30°C for a single 6-month period. Protect from light. Do not freeze.
- The reconstituted product can be stored at 15-30°C for 6 hours. Protect from direct sunlight.

MISCELLANEOUS

- Eloctate® [Antihemophilic Factor (Recombinant BDD), Fc Fusion Protein] is a fully recombinant fusion protein comprised of recombinant B domain-deleted human factor VIII (BDD FVIII) covalently linked to the Fc domain of human immunoglobulin G1. It has a longer plasma half-life than endogenous factor VIII and is dosed less frequently than the other factor VIII recombinant products.
- Eloctate® does not contain von Willebrand Factor and is not indicated in patients with von Willebrand Disease.

AVAILABILITY

- Eloctate® is available from the Blood Bank.

REFERENCES

Eloctate product monograph; Biogen July 8, 2016.
KGH Sept 2017