

FACTOR IX (RECOMBINANT) LONG ACTING

Coagulation Factor IX (recombinant), Fc Fusion Protein; Alprolix®

CLASSIFICATION

- Coagulation factor.

INDICATIONS

- Alprolix® is a long-acting anti-hemophilic factor (recombinant) indicated in adults and children with haemophilia B (congenital factor IX deficiency or Christmas disease) 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, 1000, 2000 or 3000 International Units (IU) of Coagulation Factor IX (Recombinant), Fc Fusion Protein. When diluted as directed, the reconstituted product contains 50, 100, 200, 400 and 600 IU/mL respectively. Each vial has the actual factor IX potency in IU stated on the label of each vial and the carton.
- Reconstitute each vial using the vial adapter reconstitution device and the prefilled 5 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 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).
- Headache, obstructive uropathy, oral paresthesia.
- Development of activity-neutralizing antibodies.

DOSAGE

- Refer to Alprolix® product monograph.

COMPATIBILITY, STABILITY

- Store unopened vials at 2-8°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 3 hours. Protect from direct sunlight.

MISCELLANEOUS

- Alprolix®: Coagulation Factor IX (Recombinant), Fc Fusion Protein is a long-acting, fully recombinant, fusion protein comprising human coagulation factor IX covalently linked to the Fc domain of human immunoglobulin G1. It has a longer plasma half-life than endogenous factor IX and is dosed less frequently than recombinant factor IX (BeneFIX®).

AVAILABILITY

- Alprolix® is available from the Blood Bank; not routinely stocked, but available on request.

REFERENCES

Alprolix Product Monograph; Bioverativ Canada Inc. May 17, 2017
KGH Nov 2017