IgG1 (immunoglobulin G subclass 1) is a common protein naturally found in the body.

Fc fusion uses recombinant DNA science (combining of genetic material) to link or fuse a therapeutic protein to the Fc region of IgG1.

Fc region

Therapeutic protein

Every IgG has an Fc region, which binds to the neonatal Fc receptor (FcRn) within cells.

Proteins enter the cell from the bloodstream.

The fusion to Fc can allow the therapeutic protein to bind to FcRn.

FcRn can redirect a therapeutic protein away from the lysosome – a part of the cell that breaks down the proteins – and back toward the bloodstream.

The goal is to prolong the time coagulation factor remains in the body.

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**INDICATIONS AND IMPORTANT SAFETY INFORMATION**

**Indications**

ELOCTATE [Antihemophilic Factor (Recombinant), Fc Fusion Protein] is a recombinant DNA derived, antihemophilic factor indicated in adults and children with Hemophilia A (congenital factor VIII deficiency) for: control and prevention of bleeding episodes, perioperative management (surgical prophylaxis), and routine prophylaxis to prevent or reduce the frequency of bleeding episodes. ELOCTATE is not indicated for the treatment of von Willebrand disease.

**Important Safety Information**

Do not use ELOCTATE if you have or have had an allergic reaction to it in the past.

Tell your healthcare provider if you have or have had any medical problems, take any medicines, including prescription and non-prescription medicines, supplements, or herbal medicines, have any allergies, are breastfeeding, are pregnant or planning to become pregnant, or have been told you have inhibitors (antibodies) to Factor VIII.

Allergic reactions may occur with ELOCTATE. Call your healthcare provider or get emergency treatment right away if you have any of the following symptoms: difficulty breathing, chest tightness, swelling of the face, rash, or hives.

Your body can also make antibodies called, “inhibitors,” against ELOCTATE, which may stop ELOCTATE from working properly.

Common side effects of ELOCTATE are joint pain and general discomfort. These are not all the possible side effects of ELOCTATE. Talk to your healthcare provider right away about any side effect that bothers you or that does not go away, and if bleeding is not controlled after using ELOCTATE.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see www.ELOCTATE.com for full Prescribing Information.