

**NARRATOR:** ELOCTATE [Antihemophilic Factor (Recombinant), Fc Fusion Protein]. Please see indications and important safety information at the end of this video. The ELOCTATE anti-hemophilic factor VIII recombinant, Fc Fusion protein manufacturing process is designed with purification and viral standards in mind. We use state of the art equipment in our manufacturing process. The ELOCTATE manufacturing process begins with a production of clotting factor VIII recombinant Fc Fusion protein using recombinant DNA technology in a cell line that has undergone safety and viral testing. In addition, no human or animal derived proteins are used in the purification and formulation processes. Inside the cells, recombinant DNA technology provides genetic information, instructing the cells to assemble B-domain deleted factor VIII joined or fused with Fc to form a single molecule. The cells then release ELOCTATE into the cell culture medium. Once enough protein has been produced, ELOCTATE is separated out through an extensive purification process. First, a detergent is added to the cell culture to inactivate any potential viral contaminants. Next, the cell culture solution is passed through a carefully designed column where ELOCTATE binds with a molecule called a ligand, allowing it to be separated from the rest of the solution. The remaining solution containing ELOCTATE is sent through a series of carefully designed purification columns. From there, ELOCTATE undergoes a 15 nm filtration step for removal of viruses. Lastly, the purified protein is dried into a powder that is supplied in sterile, single-use vials for patient use. From the initial production of the proteins to years after the product has been developed, Bioverativ recognizes the importance of quality standards in the production of our clotting factors. Providing an understanding of our manufacturing process is part of our commitment to patients and families in the Hemophilia community.

**Indications:** ELOCTATE is an injectable medicine that is used to help control and prevent bleeding in people with Hemophilia A (congenital Factor VIII deficiency). Your healthcare provider may give you ELOCTATE when you have surgery.

**Important Safety Information:** Do not use ELOCTATE if you 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. The most frequently occurring side effects of ELOCTATE are headache, rash, joint pain, muscle 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](http://www.fda.gov/medwatch), or call 1-800-FDA-1088. Please see Full Prescribing Information.