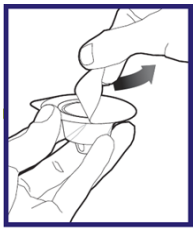
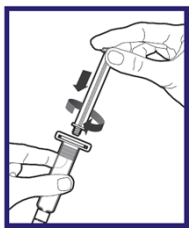
Other Names	• Antihemophilic factor VIII, extended half-life
Description	• Produced by recombinant DNA technology in a human embryonic kidney cell line. • The cell culture medium does not contain any proteins derived from animal or human sources. • Fc Fusion delays lysosomal degradation which allows for longer plasma half-life. • The purification process utilizes a series of chromatography steps that does not require the use of a monoclonal antibody. It also includes a detergent viral inactivation step and multiple viral clearance steps, including an affinity chromatography step and a 15 nm virus-retaining nanofiltration step.

Special Approvals/Authorizations	• An independent 2 person check is required for all doses. Nurses from the Manitoba Bleeding Disorder Program are exempt from the independent 2 person check.
	• A nurse may administer a dose that provides:
	  ○ Up to 200 international units greater than the prescribed dose; or
	  ○ No more than 100 international units less than the prescribed dose without receiving a new medication order.
	• Patients accustomed to self-administering factor VIII may continue to do so on the written order of a hematologist or designate.

Classification	**Special Populations:** **Pediatrics (less than 12 years of age):** No data are available for patients below the age of 12 years. **Geriatrics (greater than 65 years of age):** Clinical studies did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Dose selection for an elderly patient should be individualized (see Dosage and Administration). **Pregnant women:** Can be used in pregnancy only if the potential benefit justifies the potential risk. Animal reproductive studies have not been conducted with Eloctate, however Eloctate has been shown to cross the placenta in mice. **Nursing Women:** Experience regarding the use of factor VIII during breast-feeding is not available. Should only be administered to nursing mothers if clinically indicated.

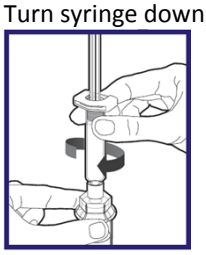
Indications	• For the control and prevention of bleeding episodes in patients with hemophilia A;
	• Not indicated for the treatment of:
	  ○ Other factor deficiencies (e.g. factor II, VII, X) or for hemophilia A patients with inhibitors to factor VIII.
	  ○ Patients with von Willebrand Disease.

Contraindications	• Contraindicated in individuals who have manifested severe hypersensitivity reactions, including anaphylaxis, to the product or its components. **WARNINGS:** • The clinical response to Eloctate, may vary. If bleeding is not controlled with recommended dose, the plasma level of factor VIII should be determined and a sufficient dose of Eloctate administered to achieve a satisfactory clinical response. • Allergic type hypersensitivity reactions, including anaphylaxis are possible with factor replacement therapies. • Inhibitors have been reported with factor replacement therapy. If the patient's plasma factor VIII level fails to increase as expected or if bleeding is not controlled after administration, the presence of an inhibitor (neutralizing antibodies) should be suspected and appropriate testing performed • Eloctate has not been studied in patients with renal or hepatic impairment.

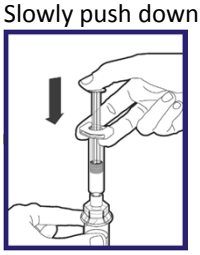
	• Eloctate has not been evaluated in animal fertility studies. It is not know whether Eloctate can affect fertility or sperm development.
Supplied	Vial size is 250 international units, 500 international units, 750 international units, 1000 international units, 1500 international units, 2000 international units and 3000 international units.
Dosage	**Usual:** Patient response and factor VIII levels guide dose. 1 international units/kg usually raises FVIII level by 2% **Treatment, Minor/Moderate Hemorrhage**: 20-30 international units/kg (target FVIII level 40-60%) **Treatment, Major/Life-Threatening Hemorrhage:** 40-50 international units/kg (target FVIII level 80-100%) **Individualized prophylaxis:** The recommended regimen is 50 international units/kg every 3 to 5 days. For weekly prophylaxis the recommended dose is 65 international units/kg.
Reconstitution/Stability	**Reconstitution:** Eloctate should be reconstituted only with the diluent syringe provided in the Eloctate package. Use aseptic technique throughout. 1. Allow vial of Eloctate and pre filled diluent syringe to reach room temperature before use. 2. Wipe top of the vial with alcohol swab; allow to dry 3. Peel lid back on vial adapter package  4. On a flat surface, place adapter over Eloctate vial and push down so that the spike punctures centre of the rubber stopper on the vial  5. Attach plunger rod to diluent syringe by inserting the rod into the syringe and turning clockwise. 

6. Hold syringe with cap pointing up; snap off cap with other hand.

7. Turn syringe down; insert tip into adapter opening on vial; turn clockwise to attach



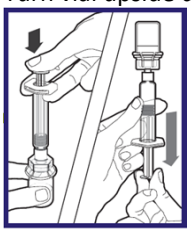
8. Slowly push down plunger of syringe to inject the diluent into the vial



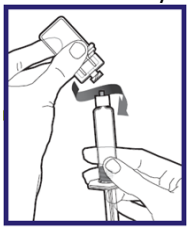
9. Swirl vial gently to dissolve the product; do not shake

10. Do not use the reconstituted Eloctate if it is cloudy or contains visible particles

11. Turn vial upside down, slowly pull plunger rod to draw solution into syringe



12. Unscrew the syringe from the vial adapter



	Stability • Stable at 2-8 °C until the expiry date indicated on the label. • May be stored at room temperature 15-30 °C for a single 6 month period • Do not freeze. • Protect from light. • After reconstitution the product can be stored at room temperature 15-30 °C for 6 hours. Infusions should be completed within 6 hours after reconstitution of the product. • Compatible with normal saline • Do NOT administer concurrently with any other product.
Compatibilities/ Incompatibilities	• No other drugs / solutions (including normal saline) can be co-administered in the same line while Eloctate is being infused
Administration, Identification and ABO Compatibility	Refer to **Manitoba Best Practice Guidelines** • section 2.2 Standards- Identification and Administration • ABO Compatibility not applicable
Administration, Method	Maximum Concentration: • Not applicable Maximum Rate: • The rate of administration should be determined by the patient's comfort level, and no faster than 10 mL/minute.
Adverse Events	• The most common adverse drug reactions observed were malaise (general discomfort) and arthalgia (joint pain) in a few people. • One subject was withdrawn from study due to an adverse drug reaction of rash. • In the clinical trials there were no reports of any anaphylactic reactions or inhibitor formation. **ADVERSE REACTIONS REPORTED:** GENERAL DISORDERS Malaise, chest pain, feeling cold, feeling hot NERVOUS SYSTEM DISORDERS Dizziness, dysgeusia, headache MUSCULOSKELETAL Arthralgia, joint swelling, myalgia GASTROINTESTINAL DISORDERS Abdominal pain (lower and upper) VASCULAR DISORDERS Angiopathy, hypertension CARDIAC DISORDERS Bradycardia, procedural hypotension RESPIRATORY DISORDERS Cough SKIN DISORDERS Rash
References:	Eloctate Product Monograph – Date of Revision: April, 2, 2015, Date of Approval: April 8, 2015 Package Insert - Eloctate
Reviewed by:	Dr. Donald Houston Dr. Jayson Stoffman