ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

ELOCTATE ®
Anti-hemophilic Factor (Recombinant)

APPLICABILITY: This document applies to APL, AHS, Covenant Health, and all other health care professionals involved in the transfusion of blood components and products in Alberta.	***Other Names:*** recombinant Factor VIII, Antihemophilic factor ***Company:*** *Sanofi* ***Class:*** *Manufactured recombinant Anti-hemophilic product, standard half-life*

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**IV Infusion**	**Continuous Infusion**	**SC**	**IM**	**OTHER**
Acceptable Routes*	Yes**	Yes	No	No	No	N/A

* Administration of blood components and blood products is a restricted activity. For specific conditions that apply to a profession's authorization to administer blood components and blood products, consult the applicable discipline-specific regulation under the Health Professions Act (Alberta). Health care professionals with this authorization require the applicable education, training and competency.

** Direct IV administration of blood products may be performed by health care professionals that have authorization of administration of blood products within their scope of practice.

DESCRIPTION:

- ELOCTATE™ is a sterile, non-pyrogenic, preservative-free, lyophilized, white to off-white powdered concentrate of fully recombinant human coagulation factor VIII for intravenous administration.
- Available in dose sizes of 250, 500, 750, 1000, 1500, 2000 and 3000 IU.
- The purification process utilizes a series of chromatography steps that does not require use of a monoclonal antibody. The process also includes a detergent viral inactivation step and multiple viral clearance steps, including an affinity chromatography step and a virus nano-filtration step. The Antihemophilic Factor protein is produced by recombinant DNA technology in a human embryonic kidney cell line. No human or animal derived additives are used in the purification and formulation processes.
- The diluent is Sterile Water for Injection and is supplied in a pre-filled syringe.

AVAILABILITY:

- Supplied by Canadian Blood Services.
- Contact your local laboratory/transfusion service regarding stock availability on site.

INDICATIONS:

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 (e.g., in trauma or procedures with increased risk of bleeding).
- Perioperative management (surgical prophylaxis).

CONTRAINDICATIONS:

- Patients with von Willebrand Disease (ELOCTATE™ does not contain von Willebrand Factor).
- Known hypersensitivity to the product or any of the constituents in the formulation of ELOCTATE™ (Polysorbate 20, Sucrose, L-Histidine, Calcium Chloride Dihydrate, and Sodium Chloride).

WARNINGS:

- Development of activity-neutralizing antibodies has been detected in patients receiving factor VIII-containing products. If expected plasma factor VIII activity levels are not attained, or if bleeding is not controlled with an appropriate dose, an assay that measures factor VIII inhibitor concentration should be performed.
- Anaphylaxis and anaphylactoid reactions are possible.

DOSE (Refer to Product Insert):

- Dose to be determined by the most responsible health practitioner (MRHP) only after consult with Hematologist or bleeding disorder clinic.
- Refer to patient's care plan or Factor First card, if available.
- Dosage must be individualized to the severity of factor VIII deficiency, location and extent of bleeding, presence of inhibitors, Factor VIII level desired, and the patient's clinical condition.
- One IU of Eloctate™ per kg body weight is expected to increase the circulating level of factor VIII by 2%.
- More frequent or higher doses may be required in children <12 years old (See product insert).

Manufacturer Recommended Dosing:

Indication	Situation	Target (% of normal FVIII)	Recommended Dosing		
Prophylaxis	Pediatric (under 12 years)	N/A	Up to 80 IU/kg every 3 to 5 days		
	Adults and adolescents (12 years and over)	N/A	25-65 IU/kg every 3 to 5 days* **Recommended regimen is 50 IU/kg every 3 to 5 days*		
On-demand	Minor and Moderate Bleeding	40-60	≥12 years	20-30 IU/kg Every 24-48 hours until bleeding resolves	
			<12 years	20-30 IU/kg Every 12-24 hours until bleeding resolves	
	Major Bleeding	80-100	≥12 years	40-50 IU/kg Every 12-24 hours until bleeding resolves	
			<12 years	40-50 IU/kg Every 8-24 hours until bleeding resolves	
Perioperative management	Minor Surgery:	50-80	≥12 years	25-40 IU/kg a single infusion may be sufficient Repeat every 24 hours as needed to control bleeding	
			<12 years	25-40 IU/kg a single infusion may be sufficient Repeat every 12-24 hours as needed to control bleeding	
	Major Surgery:	80-120	≥12 years	Preoperative: 40-60 IU/kg	Repeat dose of 40-50 IU/kg after 8-24 hours and then every 24 hours to maintain FVIII activity within the target range.
			<12 years	Preoperative: 40-60 IU/KG	Repeat dose of 40-50 IU/kg after 6-24 hours and then every 24 hours to maintain FVIII activity within the target range.
Dosage Required (IU) = Body Weight (kg) × Desired Factor VIII Increase (IU/dL or % normal) × 0.5 (IU/kg per IU/dL)					

ADMINISTRATION:

Confirm signed consent has been obtained and documented prior to requesting blood components or products (human-source) from lab/transfusion service where possible.

Pre-Infusion:

- Ensure recent patient weight and height is on file.
- Ensure pertinent labs are available as required (ie. Factor VIII).
- Ensure any ordered premedications have been given (antihistamines, antipyretics prn).
- Perform pre-transfusion checks per AHS PS-59 Transfusion of Blood Components and Blood Products Policy.
- Report any new onset acute illness to the authorized prescriber prior to commencing infusion.

Access: Eloctate® can be given via peripheral or central venous access site.

Reconstitution Supplies:

- Vial of Eloctate® Product (lyophilized powder)
- 0.9% sodium chloride (prefilled syringe* included with product)
- Vial adapter (included with product)
- Plunger rod (included with product)
- Alcohol swabs (included with product)
- Sterile plastic Luer lock syringe, large enough to contain dose if:
  - Combining multiple vials*
  - The pre-filled glass syringe with diluent is not compatible with the needless connector

Reconstitution:

- Bring the product and diluent to room temperature prior to reconstitution.
- Refer to Prefilled Syringe with Vial Adapter Reconstitution Instructions.
- Eloctate® should be visually inspected for particulate matter and discoloration prior to administration. Do not use solutions that are visibly cloudy or have deposits.

Compatible IV Solutions:

- Do not mix with other medicinal products or solutions.
- Normal saline can be used to flush the line.

Administration Supplies:

- For direct IV administration (preferred):
  - Sterile infusion set (provided in kit), if no established IV access
- For IV infusion:
  - Syringe pump and syringe pump tubing

The pre-filled glass syringe may not be compatible with all needleless connectors (e.g. ICU Medical MicroClave ® Neutral Connector). You may need to withdraw and administer the reconstituted product using a standard sterile plastic luer-lock syringe.

Administration:

- Eloctate® should be administered immediately and no later than 6 hours after reconstitution.
- **Administration rate:**
  - Administration rate should be specified by the MRHP, bleeding disorder clinic, or as determined by patient comfort.

NURSING IMPLICATIONS:

Patient Monitoring:

- Vital Signs: Pre-administration**,** on completion of dose, and as patient condition requires.
- If the patient has experienced previous adverse reaction to product transfusion, or this is the first transfusion of product for patient, monitor for 30-60 minutes post.

Patients receiving blood product transfusions must be observed closely for signs of any unexpected or untoward reactions. These reactions may occur during or after the infusion of blood or blood products. For follow up instructions to a transfusion reaction, go to: Transfusion Reactions | Alberta Health Services

Documentation:

- Ensure documentation is completed per AHS PS-59 Transfusion of Blood Components and Blood Products Policy.
- Patient tolerability should be documented in appropriate flow chart or clinical record (electronic or paper).
- Document vital signs as required in the appropriate flow chart or clinical record (electronic or paper).
- Provide patient notification documentation where required.

POTENTIAL HAZARDS WITH PARENTERAL ADMINISTRATION:

- Potential adverse events related to a blood product transfusion range in severity from minor with no sequelae to life-threatening.
- All adverse events occurring during a transfusion should be evaluated to determine whether or not the transfusion can be safely continued/restarted.
- All adverse events suspected to be related to a product transfusion (whether during or after a transfusion) must be reported to your local transfusion service.
- Allergic-type hypersensitivity reactions including anaphylaxis have been reported and have manifested as pruritis, rash, urticaria, hives, facial swelling, dizziness, hypotension, nausea, chest discomfort, cough, dyspnea, wheezing, flushing, discomfort (generalized) and fatigue.
- The most commonly reported adverse reactions in patients receiving Eloctate® are joint pain and general discomfort, muscle pain, headache, and rash.

Side Effects - Flushing - Headache - Nausea - Itching / redness at infusion site		**Action:** Slow rate of infusion
Potential Allergic Reaction - Difficulty breathing or swallowing - Chest tightness - Hives/severe itching - Swelling of lips and tongue - Dizziness - Pale and cold skin - Fast heartbeat - Red or swollen face or hands		**Action:** **STOP** infusion **IMMEDIATELY** and contact physician

STORAGE & STABILITY:

- Eloctate® may be stored at refrigerated temperatures of 2°C to 8°C until expiration date on box.
- Eloctate® may also be stored at room temperate (15°C to 30°C) for up to 6 months.
  - Product may not be returned to refrigerated temperatures after being stored at room temperature. Product must be discarded after the 6-month period.
- The reconstituted Eloctate® must be used within 6 hours after reconstitution.
- Protect from light.
- Do not freeze.

CONTACT INFORMATION:

Approved By: APL Transfusion Medicine Discipline Council

For questions or comments please contact Transfusion.SafetyTeam@aplabs.ca

REFERENCES

Sanofi-aventis Canada Inc. November 8 2021, Eloctate® product monograph. Submission Control Number: 247043. [Accessed 2023Jan31] eloctate.pdf (sanofi.ca)