Alberta Health Services

This document applies to all Covenant and AHS sites.

ELOCTATE™

Class: *Manufactured Anti-hemophilic recombinant product*

OTHER NAMES: anti-hemophilic factor (recombinant BDD), antihemorrhagic blood coagulation factor VIII

Company: Biogen Idec Canada Inc.

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

*** Professionals performing these restricted activities have received authorization from their regulatory college and have the knowledge and skill to perform the skill competently.**

**** Transfusion of Blood Components and Products Learning Module Section Three: Direct IV Administration of Blood Products. RNs may administer direct IV blood products. Not to be confused with medication administration**

DESCRIPTION OF PRODUCT:

- 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 CBS
- Contact your local laboratory/transfusion service regarding stock availability on site.

INDICATIONS FOR USE:

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):

1 IU of ELOCTATE™ per kg body weight is expected to increase, on average, the circulating level of factor VIII by 2%.

- 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.
- More frequent or higher doses may be required in children <12 years old (See product insert)
- The required dosage is calculated using the following formula:

Required units=body weight (kg) x desired factor VIII rise (IU/dl or % of normal) x 0.5 (IU/kg per IU/dl)

**** Consult with Hematologist or the bleeding disorder clinic.****

ADMINISTRATION:

Confirm written (signed) consent has been obtained and documented prior to requesting blood component from lab/transfusion service where possible.

Pre-Infusion: Ensure recent patient weight is on file and pertinent labs are available. Perform the appropriate pre-transfusion checks per protocol.

Access: ELOCTATE™ can be given via CVC, PICC, Port-a-Cath®, or peripheral IV line.

Reconstitution Supplies:

- ELOCTATE™, lyophilized in single dose vial
- Diluent (Sterile Water for Injection) in a prefilled syringe
- Vial adapter

} Contained in box

Administration Supplies:

- **For direct IV administration:**
  - Sterile infusion set (provided in kit), if no established IV access
- **For IV infusion:**
  - Syringe pump (preferred) or IV pump
  - Syringe pump tubing, or appropriate IV administration set (buretrol preferred)

Reconstitution: Refer to reconstitution steps with vial adapter at:
http://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-tm-eloctate-reconst.pdf

Administration:

- Give within a maximum of 6 hrs of reconstitution.
- **DO NOT** mix with other drugs or IV solutions.

** Included glass syringe is incompatible with ICU Medical MicroClave® Neutral Connector. Draw up reconstituted product with a sterile plastic luer-lock syringe for administration.**

Administration rate: Administration rate should be determined by the ordering physician, local bleeding disorders clinic, and as tolerated by the patient.

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) should be reported to your local transfusion service.

Side Effects	**Action**
- Flushing - Headache - Nausea - Itching and redness at the venipuncture site	Slow rate of infusion

Potential Allergic Reaction	**Action**
- Stuffy nose - Hives/severe itching - Cough - Chest pain - Wheezing - Facial swelling	**STOP** infusion **IMMEDIATELY** and contact physician

NURSING IMPLICATIONS:

Patient Monitoring:

- Vital Signs: Pre-administration**,** on completion of dose, and as patient condition requires (see administration rate).

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 to a transfusion reaction see: http://www.albertahealthservices.ca/lab/page4240.aspx Notify the transfusion service as soon as possible that an adverse reaction has occurred.

Documentation:

- Ensure documentation is completed as per the AHS *Transfusion of Blood Components and Products* procedure.
- Assessment of patient tolerability should be documented in appropriate flow chart or clinical record (electronic or paper) as required.

STORAGE & STABILITY OF PRODUCT:

- Stored at 2-8°C. **Do not freeze.**
- Protect from light.
- May be stored for a single period of up to 6 months at room temperature (15 - 30 ºC) Do not exceed expiry date. Can be returned to refrigerated storage after 6 months until expiry.
- Expiration date is indicated on bottle and packaging.
- Administer within 6 hours of reconstitution (reconstituted product can be stored at room temperature until administered)

COMMENTS:

Date Effective: 13 Sept 2019
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Approved By: APL Transfusion Medicine Discipline Council
Document Number: PTMGNR00017
For comments or questions about this document, please contact Transfusion.SafetyTeam@ahs.ca

REFERENCES

ELOCTATE™ product monograph SCN 163447

LINK to WEBSITE for PRESCRIBING INFORMATION:

http://www.biogen.ca