Eloctate

TRANSFUSION MEDICINE SERVICES

CLASSIFICATION	ALERTS
Recombinant Coagulation Factor VIII Product, Extended Half-life	None

PREPARATION and ADMINISTRATION

Eloctate is a recombinant extended half-life FVIII product that does not contain plasma therefore a blood consent is not required.

Reconstitution

Diluent: sterile water for injection

See pages 2-6 for reconstitution steps -administer within 3 hours of reconstitution

After reconstitution, inspect visually for particulate matter and discoloration prior to administration

IV Direct	Intermittent Infusion	Continuous Infusion
IV Direct is the recommended route of administration. Professionals performing these restricted activities must have received authorization from their regulatory College and have the knowledge and skill to perform the skill competently Administer reconstituted dose as determined by comfort and no faster than 10 mL/min If no indwelling IV, use the butterfly and supplies provided in the box.	**IV Bag (large volume pump)** Not Recommended **Syringe (syringe pump)** Not Recommended	**IV Bag (large volume pump)** Not applicable **Syringe (syringe pump)** Not applicable

Requirements and Monitoring

Baseline vitals before starting infusion. Reassess 15 min after infusion.

Document all vitals taken.

Blood pressure via cuff or arterial line
Temperature
Heart Rate
Respirations

Keep unopened back up bag of NS and standard IV tubing nearby for prompt response if an adverse event (AE) occurs.

INDICATIONS

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.
- Perioperative management (surgical prophylaxis)

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ADVERSE EFFECTS

Allergic-type hypersensitivity reactions have been reported and are rare. They can manifest as pruritus, rash, urticaria, local site reactions, hives, facial swelling, dizziness, hypotension, nausea, chest discomfort, cough, dyspnea, wheezing, flushing, discomfort (generalized) and fatigue.

If an AE is suspected: stop the infusion, and consult the authorized prescriber (AP) for medical management. Notify the TM lab of a suspected reaction.

- Review the product lot number, TM tag and patient ID to rule out a verification (clerical) error and that the expiry date and time has not passed.
- Resume infusion cautiously as directed by AP. Directly observe patient x5min then closely observe x10min.
- Ensure TM tag, along with a copy of the documented clinical data and interventions are sent to TM lab once infusion is discontinued or completed.

DOSAGE

Consult the Bleeding Disorders Clinic or the Hematologist on call for appropriate dosing prior to initial dose:

Ask patient if they have a Factor First card supplying the recommended treatment and dosage

(Adult) Hereditary Bleeding Disorder Clinic 902-473-5612. After hours call 902-473-2220.
(Pediatric) IWK Bleeding Disorder Clinic 902-470-8752. After hours call 1-888-470-8888.

For patient specific dosing at the IWK please see Complex Care Management Plan in the "Alerts" section under "Scanned Permanent Health Records" in the IWK MEDITECH MAGIC system.

COMPATIBILITY, STABILITY

- Compatible with NS
- Draw up reconstituted product with a sterile plastic luer-lock syringe for administration
- Single use vials. Do not use past expiry date
- Do not dilute in any IV solutions
- Prior to reconstitution, vials should be stored in their supplied box to protect from light
- Do not store unused vials in refrigerator. Administer at room temperature

DOSAGE FORMS

- Supplied by Transfusion Medicine (Blood Bank)

MISCELLANEOUS

- None

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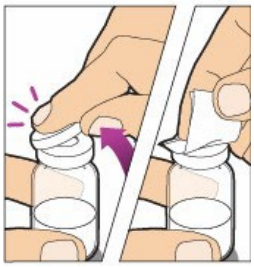
RECONSTITUTION

Use aseptic technique, a flat work surface during the reconstitution procedure and the diluent in the pre-filled syringe supplied in the package. Don clean gloves.

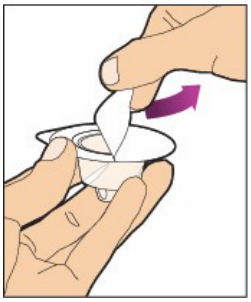
Actual factor VIII activity in International Units is stated on the label of each Eloctate carton and vial.

1. If refrigerated, allow the vial of Eloctate and pre-filled diluent syringe to reach room temperature before use.

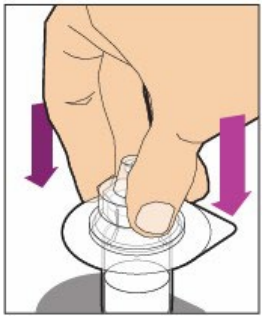
2. Remove the plastic cap from the Eloctate vial and wipe the rubber stopper of the vial with an alcohol wipe. Allow the rubber stopper to dry. After cleaning, do not touch the rubber stopper with your hand or allow it to touch any surface.



3. Completely remove the backing from the vial adapter package by peeling back the lid. Do not remove the vial adapter from the package or touch the inside of the package of the adapter.



4. Keep the vial on a flat surface. Hold the vial adapter package with one hand and using the other hand, place the vial adapter over the vial. The spike should be placed directly above the centre of the rubber stopper. Push the vial adapter straight down until the adapter spike punctures the centre of the vial stopper and is fully inserted.



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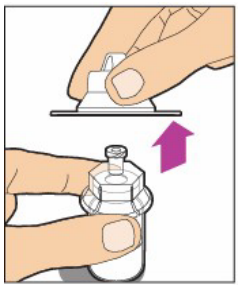
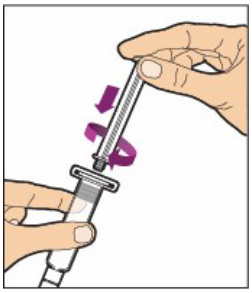
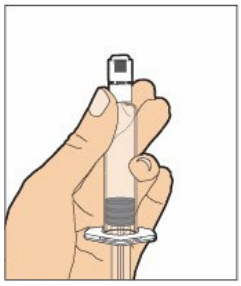
5. Lift the package cover away from the vial adapter and discard the cover.



6. Hold the plunger rod at the circular disk. Place the tip of the plunger rod into the end of the syringe. Turn in a clockwise motion until it is securely attached. Only use the diluent syringe provided to reconstitute the drug product.



7. With one hand, hold the diluent syringe right under the cap, and with the cap pointing up. Make sure you are holding the diluent syringe by the ridged part directly under the cap. Do not use if the cap has been removed or is not securely attached.



8. With your other hand, grasp the cap and bend it at a 90˚ angle until it snaps off. After the cap snaps off, you will see the glass tip of the syringe. Do not touch the glass tip of the syringe or inside of the cap.

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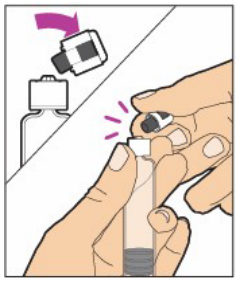
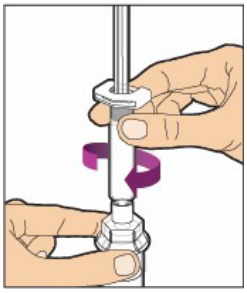
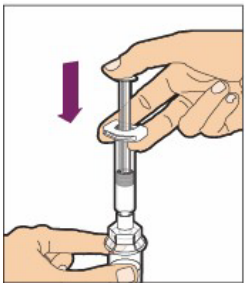


9. Be sure the vial is sitting on a flat surface. Insert the tip of the syringe into the adapter opening. Turn the syringe in a clockwise motion until it is securely attached to the adapter.



10. Slowly depress the plunger rod to inject all of the diluent into the vial. The plunger rod may rise slightly after this process. This is normal.



11. With the syringe still connected to the adapter, gently swirl the vial until the product is completely dissolved. The appearance of the solution should be clear to slightly opalescent and colorless. Do not shake. Do not use the reconstituted Eloctate if it contains visible particles or is cloudy.

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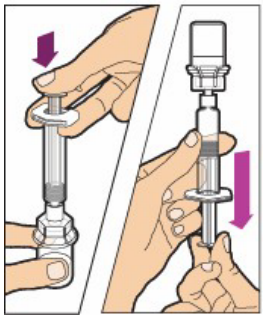
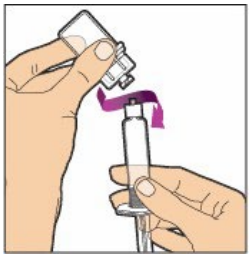
12. Make sure the plunger rod is completely depressed. Turn the vial upside-down. Slowly pull on the plunger rod to draw the solution into the syringe. Be careful not to pull the plunger rod completely out of the syringe.



13. Gently unscrew the syringe from the vial adapter and dispose of the vial with the adapter still attached. Do not touch the syringe tip or the inside of the cap. Reconstituted Eloctate should be administered as soon as possible.



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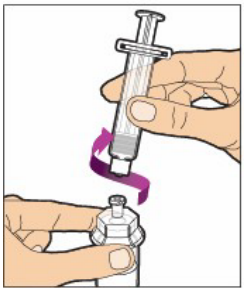
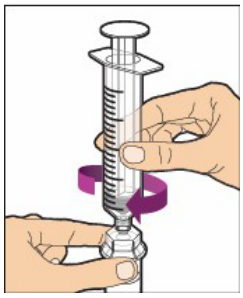
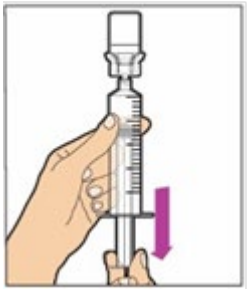
Pooling

If you are using two or more vials of Eloctate with the same lot numbers, you can follow these pooling steps. Be sure to leave the vial adapter attached to the vial, as you will need it for attaching a large luer lock syringe. Do not detach the diluent syringe or the large luer syringe until you are ready to attach the large luer lock syringe to the next vial (with vial adapter attached).

1. Remove the diluent syringe from the vial adapter by turning it counterclockwise until it is completely detached.	
2. Attach a separate large luer lock syringe by turning clockwise until it is securely attached.	
3. Slowly pull on the plunger rod to draw the solution into the syringe. Repeat this pooling procedure with each vial you will be using. Once you have pooled the required dose, proceed to administration using the large luer lock syringe.	

REFERENCES

- CL-BP-030, IWK-625 Blood Component and Blood Product Administration – Policy and Procedure
- Eloctate product monograph. Found at https://www.sanofi.ca/en/products-and-resources/prescription-products