

ELOCTATE® (E-lok-tate)

efmoroctocog alfa (rhu)

Recombinant coagulation factor VIII Fc fusion protein 250, 500, 1000, 2000, 3000 IU/vial for IV infusion

Directions for Use

Read all the instructions before you start. If you have any questions about this guide, ask your doctor or pharmacist. Your healthcare provider should show you or your caregiver how to reconstitute and administer ELOCTATE the first time ELOCTATE is used.

There are 5 steps, explained in this guide:

A. Setting up

B. Reconstituting the injection

C. Pooling

D. Giving the injection

E. Post-Infusion Care & Disposal

Take time to read through each section and keep this leaflet with your medicine as a reminder of what to do.

A. Setting up

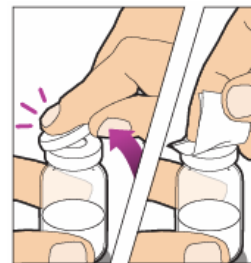
A1. First ensure that your work area is clean.

A2. Collect everything you will need. Check the expiry date on the ELOCTATE kit. If it is out of date, do not use it and contact your pharmacy immediately. If refrigerated, allow the vial of ELOCTATE and the pre-filled diluent syringe to warm to room temperature (15°C to 30°C) for approximately 30 minutes. Do not use heat sources (for example, hot water or a heater) to warm the contents.

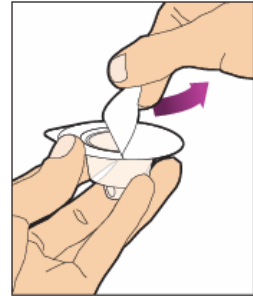
A3. Wash your hands thoroughly with soap and water before performing the following procedures.

A4. Use aseptic technique (clean and germ-free) and a flat work surface during the reconstitution procedure.

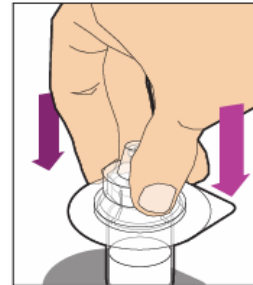
A5. Remove the plastic cap from the ELOCTATE vial and wipe the rubber stopper of the vial with an alcohol wipe. Allow the rubber stopper to dry. After cleaning, do not touch the rubber stopper with your hand or allow it to touch any surface.



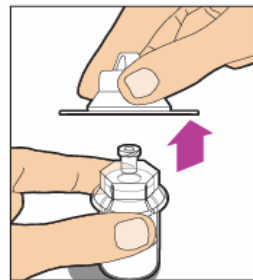
A6. Completely remove the backing from the vial adapter package by peeling back the lid. **Do not remove the vial adapter from the package or touch the inside of the package or the adapter.**



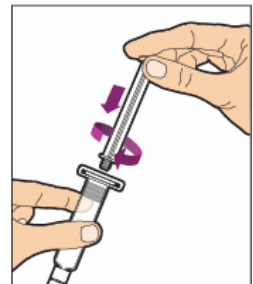
A7. Keep the vial on a flat surface. Hold the vial adapter package with one hand and using the other hand, place the vial adapter over the vial. The spike should be placed directly above the centre of the rubber stopper. Push the vial adapter straight down until the adapter spike punctures the centre of the vial stopper and is fully inserted.



A8. Lift the package cover away from the vial adapter and discard the cover.

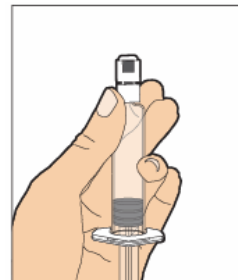


A9. Take the plunger rod and syringe out of the package. Hold the plunger rod at the circular disk. Place the tip of the plunger rod into the end of the syringe. Turn in a clockwise direction until it is securely attached. Only use the diluent syringe provided to reconstitute the drug product.

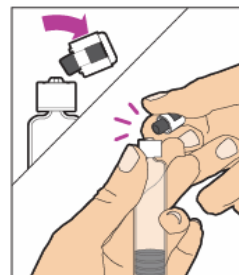


B. Reconstituting the injection

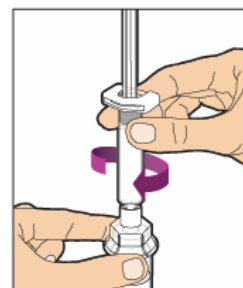
B1. With one hand, hold the diluent syringe right under the cap, and with the cap pointing up. Make sure you are holding the diluent syringe by the ridged part directly under the cap. **Do not use if the cap has been removed or is not securely attached.**



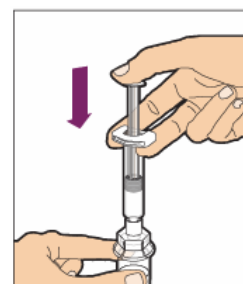
B2. With your other hand, grasp the cap and bend it at a 90° angle until it snaps off. After the cap snaps off, you will see the glass tip of the syringe. **Do not touch the glass tip of the syringe or the inside of the cap.**



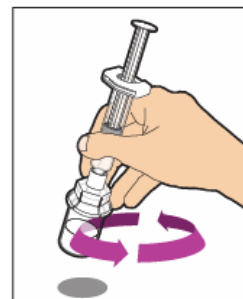
B3. Be sure the vial is sitting on a flat surface. Insert the tip of the syringe into the adapter opening. Turn the syringe in a clockwise direction until it is securely attached to the adapter.



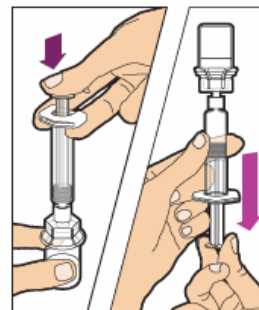
B4. Slowly depress the plunger rod to inject all of the diluent into the vial. The plunger rod may rise slightly after this process. This is normal.



B5. 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 colourless. **Do not shake. Do not use the reconstituted ELOCTATE if it contains visible particles or is cloudy.**

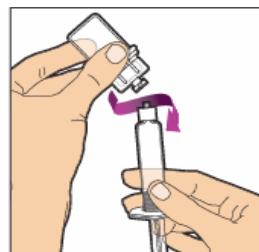


B6. Make sure the plunger rod is completely depressed. Turn the vial upside-down. Slowly pull on the plunger rod to draw the solution into the syringe. **Be careful not to pull the plunger rod completely out of the syringe.**



B7. 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.**

B8. Your ELOCTATE is now ready to be connected to your infusion tubing set. See section D below. Reconstituted ELOCTATE should be administered as soon as possible.



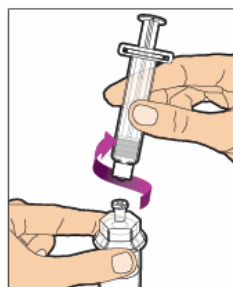
C. Pooling

If you are using two or more reconstituted vials of ELOCTATE, you can follow these pooling steps.

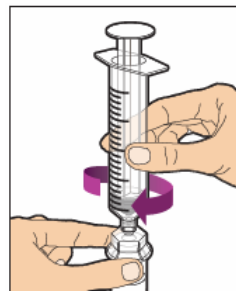
C1. Be sure to leave the vial adapter attached to the vial, as you will need it for attaching a large luer lock syringe.

C2. Do not detach the diluent syringe or the large luer lock syringe until you are ready to attach the large luer lock syringe to the next vial (with vial adapter attached).

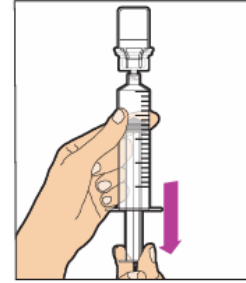
C3. Remove the diluent syringe from the vial adapter by turning it counter-clockwise until it is completely detached



C4. Attach a separate large luer lock syringe by turning clockwise until it is securely attached.



C5. 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.



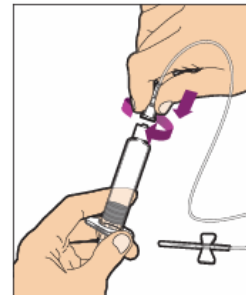
D. Giving the injection

For Intravenous Use only after Reconstitution

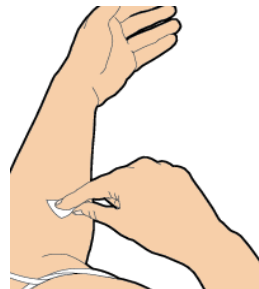
ELOCTATE is administered by intravenous (IV) infusion after reconstitution of the drug powder with the diluent.

Do not administer reconstituted ELOCTATE if it contains visible particles, is discoloured, or is cloudy.

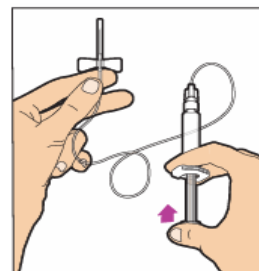
D1. Attach the syringe to the connector end of the infusion set tubing by turning clockwise until it is securely attached. **Do not administer reconstituted ELOCTATE in the same tubing or container with other medicinal products. Do not remove the protective needle cover until you are ready to insert the needle (see section D4 below)**



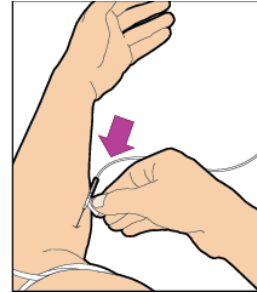
D2. Apply a tourniquet and clean the skin area where you will perform the infusion using an alcohol wipe.



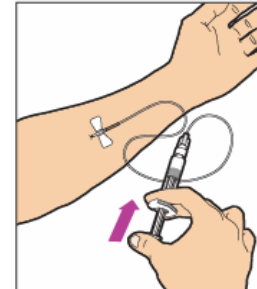
D3. Depress the plunger until all air is removed from the syringe and ELOCTATE has reached the end of the infusion set tubing. Do not push ELOCTATE through the needle.



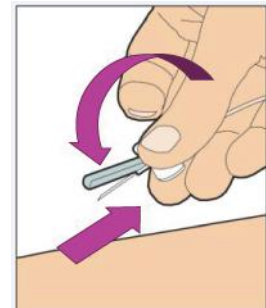
D4. Remove the protective needle cover from the infusion set tubing. Insert the needle on the infusion set tubing into the vein. Remove the tourniquet. Always verify proper needle placement when performing intravenous administration.



D5. Slowly depress the plunger on the syringe to administer ELOCTATE. ELOCTATE should be injected intravenously over several minutes. The rate of administration should be determined by your comfort level. The small amount of drug product left in the infusion set will not affect treatment.

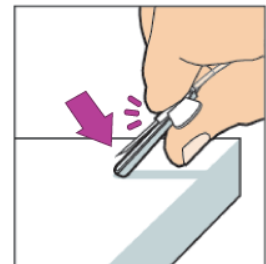


D6. After infusing ELOCTATE, flip the safety shield towards the needle. Remove the infusion set.



E. Post-Infusion Care & Disposal

E1. Place the wing and the safety shield between your thumb and index finger. Press the safety shield against a hard surface until an audible click is heard.



E2. Use a sterile gauze to put pressure on the infusion site for several minutes. Apply an adhesive bandage if necessary.



E3. A sharps bin should be used for disposal of all unused solution, empty vials and used needles and syringes.