

ELOCTATE® Rx Only
Antihemophilic Factor (Recombinant), Fc Fusion Protein

INSTRUCTIONS FOR USE

Read the Instructions for Use before you start using ELOCTATE and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Your healthcare provider should show you or your caregiver how to reconstitute and administer ELOCTATE the first time ELOCTATE is used.

Check the expiration date on the ELOCTATE kit.

Do not use the product if past the expiration date.

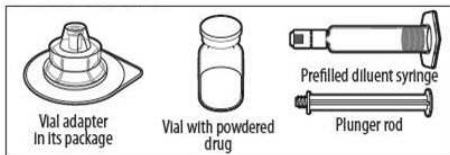
Allow the ELOCTATE vial and the diluent to come to room temperature.

Do not use external heat sources such as putting the vial and/or diluent in hot water.

Find a clean, flat work surface and collect all the supplies you will need to reconstitute and administer ELOCTATE.

Wash your hands with soap and water. *Aseptic technique* (clean and germ free) should be used.

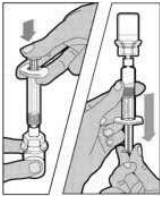

YOUR KIT CONTAINS:



RECONSTITUTION

<p>Step 1 Remove the plastic cap from the ELOCTATE vial.</p> <p>Wipe the rubber stopper of the vial with an alcohol wipe and allow it to dry.</p> <p>After cleaning, do not touch the rubber stopper with your hand or allow it to touch any surface.</p>	
<p>Step 2 Completely remove the backing from the vial adapter package by peeling back the lid.</p> <p>Do not remove the vial adapter from the package or touch the inside of the vial adapter.</p>	
<p>Step 3 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.</p> <p>The spike should be placed directly above the center of the rubber stopper.</p> <p>Push the vial adapter straight down until the adapter spike punctures the center of the vial stopper and is fully inserted.</p>	
<p>Step 4 Lift the package cover away from the vial adapter and discard the cover.</p>	

<p>Step 5 Only use the diluent syringe provided to reconstitute the drug product.</p> <p>Hold the plunger rod at the circular disk.</p> <p>Place the tip of the plunger rod into the end of the syringe.</p> <p>Turn in a clockwise motion until it is securely attached.</p>	
<p>Step 6 With one hand, hold the diluent syringe right under the cap, and with the cap pointing up.</p> <p>Make sure you are holding the diluent syringe by the ridged part directly under the cap.</p> <p>Do not use if the cap has been removed or is not securely attached.</p>	
<p>Step 7 With your other hand, grasp the cap and bend it at a 90° angle until it snaps off.</p> <p>After the cap snaps off, you will see the glass tip of the syringe.</p> <p>Do not touch the glass tip of the syringe or inside of the cap.</p>	
<p>Step 8 Be sure the vial is sitting on a flat surface. Insert the tip of the syringe into the adapter opening.</p> <p>Turn the syringe in a clockwise motion until it is securely attached to the adapter.</p>	
<p>Step 9 Slowly depress the plunger rod to inject all of the diluent into the vial.</p> <p>The plunger rod may rise slightly after this process. This is normal.</p>	
<p>Step 10 With the syringe still connected to the adapter, gently swirl the vial until the product is completely dissolved.</p> <p>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.</p> <p><i>If you are using more than one vial, stop here and proceed to the Pooling Instructions on the back.</i></p>	

<p>Step 11 Make sure the plunger rod is completely depressed.</p> <p>Turn the vial upside-down.</p> <p>Slowly pull on the plunger rod to draw the solution into the syringe.</p> <p>Be careful not to pull the plunger rod completely out of the syringe.</p>	
<p>Step 12 Gently unscrew the syringe from the vial adapter and dispose of the vial with the adapter still attached.</p> <p>Do not touch the syringe tip or the inside of the cap.</p> <p><i>Reconstituted ELOCTATE should be administered as soon as possible.</i></p>	

TURN OVER FOR POOLING AND ADMINISTRATION




TURN OVER TO FRONT SIDE FOR RECONSTITUTION

POOLING

POOLING is the process of combining two or more reconstituted vials into a larger syringe (not into the diluent syringe) prior to intravenous administration.

If you are using two or more vials, 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).

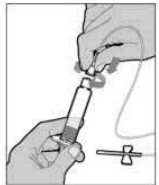

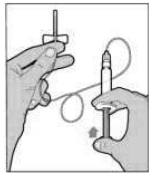


<p>Step 1 Remove the diluent syringe from the vial adapter by turning it counterclockwise until it is completely detached.</p>	
<p>Step 2 Attach a separate large luer lock syringe by turning clockwise until it is securely attached.</p>	
<p>Step 3 Slowly pull on the plunger rod to draw the solution into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

ADMINISTRATION (Intravenous Injection)

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

Your healthcare provider should teach you how to infuse ELOCTATE. Once you have been taught to self-infuse, you can follow these instructions.

Do not administer reconstituted ELOCTATE if it contains particulate matter, is discolored, or is cloudy.

<p>Step 1 Attach the syringe to the connector end of the infusion set tubing by turning clockwise until it is securely attached.</p> <p>Do not administer reconstituted ELOCTATE in the same tubing or container with other medicinal products.</p>	
<p>Step 2 Apply a tourniquet and clean the skin area where you will perform the infusion using an alcohol wipe.</p>	
<p>Step 3 Depress the plunger until all air is removed from the syringe and ELOCTATE has reached the end of the infusion set tubing.</p> <p>Do not push ELOCTATE through the needle.</p>	
<p>Step 4 Remove the protective needle cover from the infusion set tubing.</p> <p>Insert the needle on the infusion set tubing into the vein.</p> <p>Remove the tourniquet.</p> <p>Always verify proper needle placement when performing intravenous administration.</p>	
<p>Step 5 Slowly depress the plunger on the syringe to administer ELOCTATE.</p> <p><i>ELOCTATE should be injected intravenously over several minutes.</i></p> <p><i>The rate of administration should be determined by your comfort level.</i></p> <p><i>The small amount of drug product left in the infusion set will not affect treatment.</i></p>	

Step 6

After infusing ELOCTATE, remove the infusion set and use a sterile gauze to put pressure on the infusion site for several minutes.

Apply an adhesive bandage if necessary.

Dispose of all unused solution, empty vial(s), and other used medical supplies in an appropriate medical waste container.

**STORAGE CONDITIONS - PRODUCT KIT**

Keep refrigerated until use.

Keep away from direct sunlight.

STORAGE CONDITIONS - RECONSTITUTED

ELOCTATE should be administered within 3 hours after reconstitution.

Do not refrigerate after reconstitution.

Keep away from direct sunlight.

This Instructions for Use has been approved by the US Food and Drug Administration.

Manufactured by:

Bioverativ Therapeutics Inc.

Waltham, MA 02451

A SANOFI COMPANY

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For more information go to www.ELOCTATE.com or call 1-855-693-5628

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