

STORING ELOCTATE

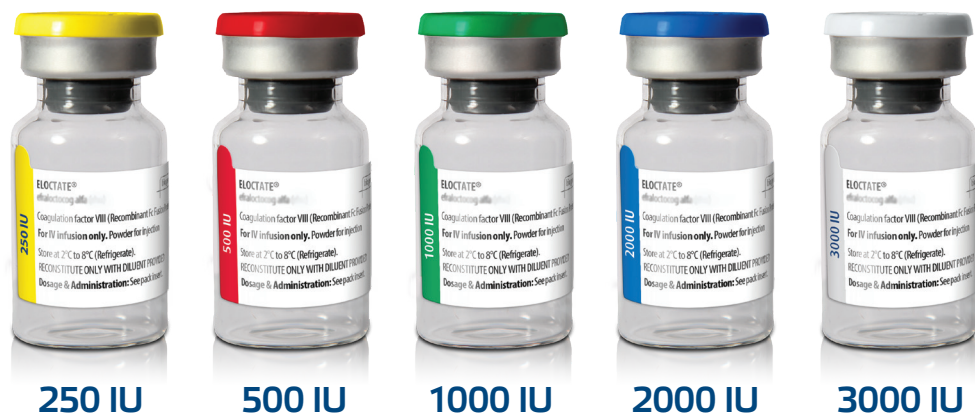
Before reconstitution

Protect from light. Unopened vials should be stored under controlled refrigeration (2°C - 8°C). The product may be stored at room temperature (up to 30°C) for a single 6 month period. The date that the product is removed from refrigeration should be noted on the carton. The product must be used or discarded before the end of this period. Do not freeze the pre-filled syringe.

After reconstitution

The reconstituted product can be stored at room temperature (30°C) for 6 hours. Protect product from direct sunlight. If product is not used within 6 hours, it must be discarded. The appearance of the reconstituted product should be clear to slightly opalescent and colourless. Dispose of all the materials in accordance with local requirements.

For further information on the reconstitution, administration and storage of ELOCTATE please refer to the leaflet contained within each product pack.



For further information about your treatment
see your haemophilia treatment centre

SANOI GENZYME

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 **ELOCTATE®**
efmoroctocog alfa

RECONSTITUTION GUIDE

- Every ELOCTATE reconstitution kit includes:
- Single-use vial containing lyophilised powder for reconstitution
 - Prefilled diluent syringe with plunger
 - Sterile reconstitution adapter



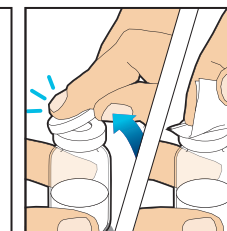
GETTING READY

- 1 First ensure that your work area is clean.
- 2 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 If it is out of date, do not use it and contact your haemophilia treatment centre or pharmacy immediately.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.

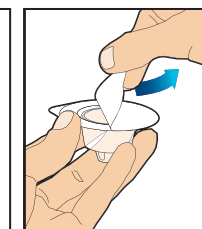
- 3 Wash your hands thoroughly with soap and water before performing the following procedures.
- 4 Use aseptic technique (clean and germ-free) and a flat work surface during the reconstitution procedure.

SETTING UP

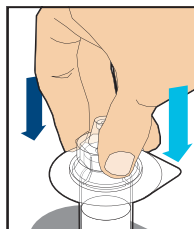
- 1 Remove the plastic cap from the ELOCTATE vial and wipe the rubber stopper of the vial with an alcohol wipe. Allow the rubber stopper to dry. After cleaning, do not touch the rubber stopper with your hand or allow it to touch any surface.



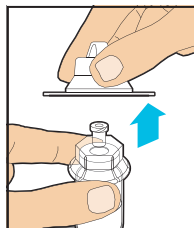
- 2 Completely remove the backing from the vial adapter package by peeling back the lid. **Do not remove the vial adapter from the package or touch the inside of the package or the adapter.**



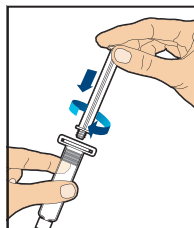
3 Keep the vial on a flat surface. Hold the vial adapter package with one hand and using the other hand, place the vial adapter over the vial. The spike should be placed directly above the centre of the rubber stopper. Push the vial adapter straight down until the adapter spike punctures the centre of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



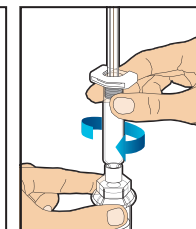
4 Lift the package cover away from the vial adapter and discard the cover.



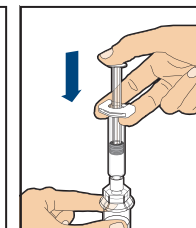
5 Take the plunger rod and syringe out of the package. Hold the plunger rod at the circular disk. Place the tip of the plunger rod into the end of the syringe. Turn in a clockwise direction until it is securely attached. Only use the diluent syringe provided to reconstitute the clotting factor product.



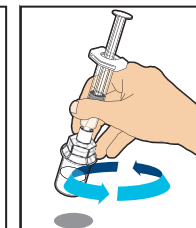
3 Be sure the vial is sitting on a flat surface. Insert the tip of the syringe into the adapter opening. Turn the syringe in a clockwise direction until it is securely attached to the adapter.



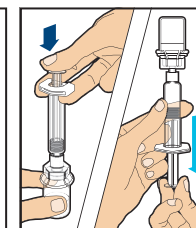
4 Slowly depress the plunger rod to inject all of the diluent into the vial. The plunger rod may rise slightly after this process. This is normal.



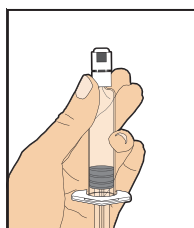
5 With the syringe still connected to the adapter, gently swirl the vial until the product is completely dissolved. The appearance of the solution should be clear to slightly opalescent and colourless. **Do not shake. Do not use the reconstituted ELOCTATE if it contains visible particles or is cloudy.**



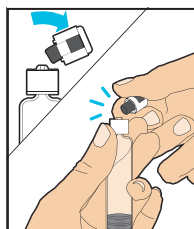
6 Make sure the plunger rod is completely depressed. Turn the vial upside-down. Slowly pull on the plunger rod to draw the solution into the syringe. **Be careful not to pull the plunger rod completely out of the syringe.**



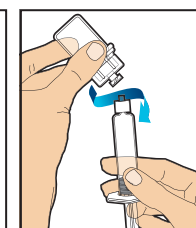
1 With one hand, hold the diluent syringe right under the cap, and with the cap pointing up. Make sure you are holding the diluent syringe by the ridged part directly under the cap. **Do not use if the cap has been removed or is not securely attached.**



2 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.**



7 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.**



8 Your ELOCTATE is now ready to be connected to your infusion tubing set. Reconstituted ELOCTATE should be administered as soon as possible.

'STORING ELOCTATE'
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RECONSTITUTING THE INJECTION