

INSTRUCTIONS FOR USE
ALTUVIIIIO® (al too'vee oh)
 [antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehnl]
 for intravenous use after reconstitution only
 Single-dose vial

Rx Only

Read the Instructions for Use before you start using ALTUVIIIIO 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 mix (reconstitute) and give ALTUVIIIIO the first time ALTUVIIIIO is used.

Any further questions? Ask your healthcare provider or call 1-800-633-1610.

Important Information You Need to Know Before Injecting ALTUVIIIIO

It is important that you do not try to inject ALTUVIIIIO unless you have received training from a healthcare provider.

- Read all of the instructions carefully before using the ALTUVIIIIO.
- ALTUVIIIIO is supplied as a single-dose vial of powder for mixing (reconstitution). Before you inject ALTUVIIIIO, you must mix (reconstitute) ALTUVIIIIO powder with liquid (diluent) that comes in a prefilled diluent syringe.
- After the powder and diluent are mixed the medicine is given in the vein (intravenous injection).
- The vial and the diluent syringe are not made with natural rubber latex.
- **Do not** use ALTUVIIIIO if it has been dropped on a hard surface or damaged.
- **Do not** use if the syringe cap has been removed or is not securely attached.
- **Do not** use the mixed ALTUVIIIIO if it contains visible particles or is cloudy.
- **Do not** give mixed ALTUVIIIIO in the same tubing or container with other medicines.

Storing ALTUVIIIIO

- Keep unused ALTUVIIIIO kit in the original carton and store in the refrigerator between 2°C and 8°C (36°F and 46°F). The product may be stored at room temperature up to 30°C (86°F). If stored at room temperature, the product (prior to mixing) expires after 6 months or after the expiration date on the product vial, whichever is earlier.
- Remove the product kit from the refrigerator and allow the ALTUVIIIIO vial and the prefilled diluent syringe to come to room temperature prior to injection.
- **Do not** use external heat sources such as putting the vial or prefilled diluent syringe in hot water.
- **Do not** return room temperature ALTUVIIIIO to refrigerator.
- Keep away from direct sunlight.
- **Do not** freeze.

Storing of Mixed (Reconstituted) ALTUVIIIIO

- ALTUVIIIIO should be given within **3 hours** after mixing.
- Keep away from direct sunlight.
- Do not refrigerate after mixing.
- Keep ALTUVIIIIO and all medicines out of the reach of children.

Preparing to Inject ALTUVIIIIO
Mixing (Reconstitution)
 Step 1:

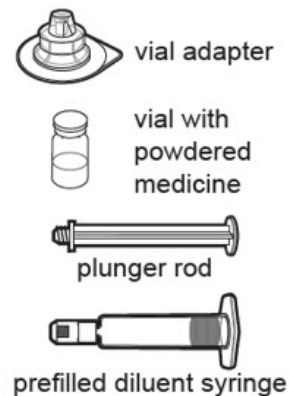


Look at the ALTUVIIIIO kit:

- Check that you have the correct medicine and dose.
- Check the expiration date.

▲**Do not** use ALTUVIIIIO if the expiration date has passed.

Step 2:



not included in the carton:



Wash your hands with soap and water.

Find a clean, flat work surface. Remove the supplies from the carton:

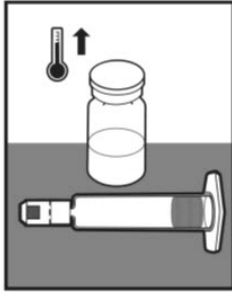
- Vial adapter in its package
- Vial with powdered medicine
- Plunger rod
- Prefilled diluent syringe

Also ensure you have the following supplies (not included in the carton):

- Infusion set
- Tourniquet
- 2 alcohol wipes
- 1 cotton ball or gauze pad
- 1 adhesive bandage, if required (See Step 22)
- 1 tape, if required (See Step 20)
- 1 larger luer lock syringe, if required (See Step 13)
- FDA-cleared sharps disposal container (See Step 23)

▲**Do not** use ALTUVIIIIO (vial or prefilled diluent syringe) if it has been dropped on a hard surface or damaged.

Step 3:



Allow the ALTUVIIIIO vial and the prefilled diluent syringe to come to room temperature before use.

▲**Do not** use external heat sources such as putting the vial or prefilled diluent syringe in hot water.

▲**Do not** put ALTUVIIIIO in direct sunlight.

▲**Do not** return room temperature ALTUVIIIIO to the refrigerator.

Step 4:



Remove the plastic cap from the ALTUVIIIIO vial.

Wipe the rubber stopper of the vial with an alcohol wipe and allow it to dry.

▲After cleaning, **do not** touch the rubber stopper with your hand or allow it to touch any surface.

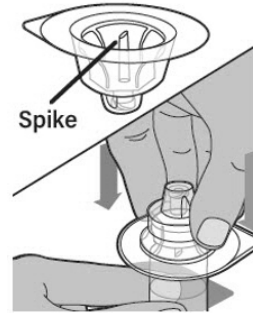
Step 5:



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 vial adapter.

Step 6:

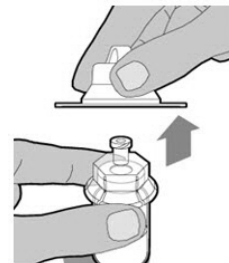


Keep the vial on a flat surface. Hold the vial with one hand and using the other hand, place the vial adapter in its package over the vial.

Note: The spike should be placed directly above the center of the rubber stopper.

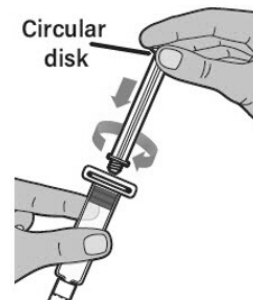
- Push the vial adapter straight down until the spike on the vial adapter punctures the center of the vial stopper and is fully inserted.

Step 7:



Lift the package cover away from the vial adapter and throw away the cover.

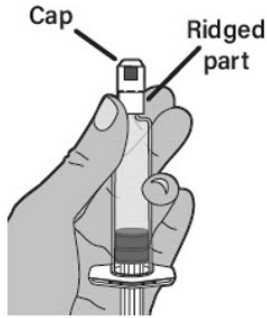
Step 8:



Note: Only use the prefilled diluent syringe provided to mix (reconstitute) the powdered medicine.

- Hold the plunger rod by the circular disk.
- Place the tip of the plunger rod into the end of the prefilled diluent syringe.
- Turn the plunger rod to the right until it is firmly attached.

Step 9:

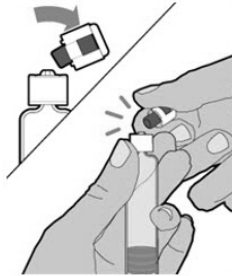


With one hand, hold the prefilled diluent syringe directly under the cap with the cap pointing up.

Note: Make sure you are holding the prefilled diluent syringe by the ridged part directly under the cap.

▲**Do not** use if the cap has been removed or is not securely attached.

Step 10:



With your other hand, grasp the cap and bend it at a 90-degree angle until it snaps off.

Note: After the cap snaps off, you will see the glass tip of the prefilled diluent syringe.

▲**Do not** touch the glass tip of the prefilled diluent syringe or the inside of the cap.

Step 11:



Note: Be sure the vial is sitting on a flat surface.

- Insert the tip of the prefilled diluent syringe into the vial adapter opening.
- Turn the prefilled diluent syringe to the right until it is securely attached to the vial adapter.

Step 12:



Slowly push down on the plunger rod to inject all of the liquid (diluent) from the prefilled diluent syringe into the vial.

Note: The plunger rod may rise slightly afterward. This is normal.

Step 13:



With the prefilled diluent syringe still connected to the adapter, gently swirl the vial until the powder is completely dissolved.

Check the solution through the vial to make sure the powder is fully dissolved.

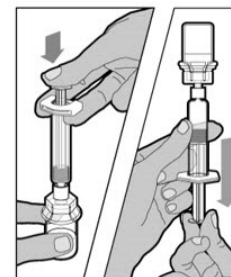
Note: The solution should look clear and colorless to slightly yellowish.

▲**Do not** shake.

▲**Do not** use the mixed (reconstituted) ALTUVIIIIO if it contains visible particles or is cloudy.

POOLING: pooling is the process of combining two or more reconstituted vials into a larger luer lock syringe (not provided in the carton). If the dose requires more than one vial, reconstitute each vial as described above (See Steps 4–13) with the prefilled diluent syringe provided. **Do not** detach the prefilled diluent syringe until you are ready to attach the larger luer lock syringe to the next vial. Keep the vial adapter attached to the vial as you will need it for attaching a larger luer lock syringe. Use a larger luer lock plastic syringe to combine the contents of the reconstituted vials into the syringe, similar as described in Steps 14–15. Repeat this pooling procedure with each vial you will be using. Once you have pooled the required dose, proceed with Step 16 (Injecting ALTUVIIIIO) using the larger luer lock syringe.

Step 14:



Make sure the plunger rod is pressed all the way down and the syringe is firmly attached to the vial adapter.
Turn the vial upside-down.

Slowly pull down on the plunger rod to draw all the solution from the vial into the syringe.

Note: Be careful not to pull the plunger rod completely out of the syringe.

Step 15:



Gently unscrew the syringe from the vial adapter by turning it to the right.

Throw away (dispose of) the vial with the adapter still attached (See Step 23).

If you are not ready to inject, put the syringe cap carefully back onto the syringe tip.

▲Do not touch the syringe tip or the inside of the cap.

Note: Mixed (reconstituted) ALTUVIIIIO should be given within 3 hours after mixing.

Protect from direct sunlight. Do not refrigerate after reconstitution.

Injecting ALTUVIIIIO

ALTUVIIIIO is given in the vein (intravenous injection) after mixing (reconstitution) of the powdered medicine with the diluent.

These are very generic instructions so your healthcare provider should teach you how to inject ALTUVIIIIO. After you have been taught to self-inject, you can follow these instructions.

▲Do not give mixed (reconstituted) ALTUVIIIIO if it contains particles, is discolored, or is cloudy.

Step 16:

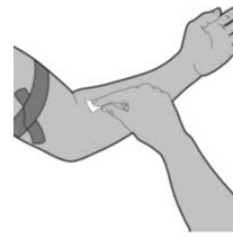


Using aseptic technique (clean and germ free), attach the syringe to the connector end of the infusion set tubing by turning it to the right until securely attached.

▲Do not give mixed (reconstituted) ALTUVIIIIO in the same tubing or container with other medicines.

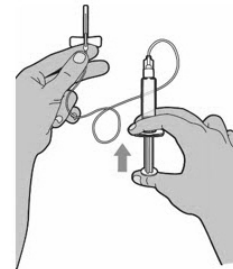
Note: Ask your healthcare provider which infusion set can be used with ALTUVIIIIO.

Step 17:



Apply a tourniquet to the upper arm. Then, using a new alcohol wipe, clean the skin where you will insert the needle and wait for it to dry.

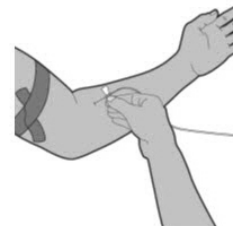
Step 18:



Prime the syringe and the tubing. Push the plunger rod until all air is removed from the syringe and ALTUVIIIIO has filled the infusion set needle.

▲Do not push ALTUVIIIIO through the needle.

Step 19:

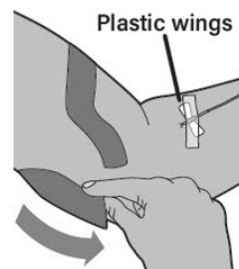


Remove the protective needle cover from the infusion set needle and throw away (discard it).

▲Do not touch the needle and do not put the needle cover back onto needle after use.

- Insert the needle on the infusion set tubing into the vein as instructed by your healthcare provider.

Step 20:

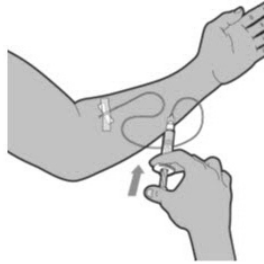


Use tape to secure the plastic wings of the needle in place at the injection site if needed.

Remove the tourniquet.

Note: Always make sure you have correctly inserted the needle into a vein when you perform an intravenous injection.

Step 21:

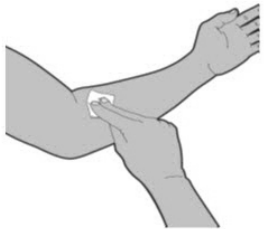


Slowly push the plunger rod on the syringe all the way down to give ALTUVIIIIO.

Your healthcare provider will provide your rate of administration based on your comfort level and the minimum injection time recommendation per vial.

Note: A small amount of medicine will be left in the infusion set after injection. This is normal.

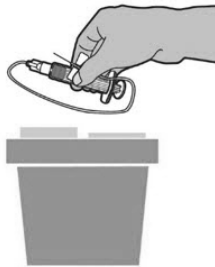
Step 22:



After delivering ALTUVIIIIO, remove the tape and the needle from the vein. Use a cotton ball or gauze pad to put pressure on the injection site for several minutes to stop any bleeding.

Note: You may apply an adhesive bandage if needed.

Step 23:



Put the infusion set and the syringe in FDA-cleared sharps disposal container right away after use.

Dispose of all unused solution according to your local regulations. Dispose of all empty vial(s), and other used medical supplies in your household trash.

▲**Do not** throw away (dispose of) the infusion set or syringe in your household trash.

Disposing of ALTUVIIIIO

Throw away (dispose of) the infusion set and the syringe in FDA-cleared sharps disposal container right away after use.

If you do not have FDA-cleared sharps disposal container you may use a household container that is:

- made of a heavy-duty plastic,
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,

- upright and stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.

When your FDA-cleared sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of FDA-cleared sharps disposal container. There may be state or local laws about how you should throw away used ALTUVIIIIO supplies.

▲**Do not** dispose of your used FDA-cleared sharps disposal container in your household trash unless your community guidelines permit this.

▲ **Do not** recycle your used FDA-cleared sharps disposal container.

Keep your FDA-cleared sharps disposal container out of the reach of children.

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

Manufactured by:
Bioerativ Therapeutics Inc.
Waltham, MA 02451
A SANOFI COMPANY
US License Number 2078

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For more information go to www.ALTUVIIIIO.com or call 1-800-633-1610

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