

## Patient Medication Information

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

#### PrALTUVIIIIO

Antihemophilic Factor VIII (Recombinant, B-Domain deleted), Fc-VWF-XTEN fusion protein

Read this carefully before you start taking ALTUVIIIIO and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about ALTUVIIIIO.

#### What is ALTUVIIIIO used for?

ALTUVIIIIO is an injectable medicine that is used to help control and prevent bleeding in people with hemophilia A (congenital factor VIII deficiency).

#### How does ALTUVIIIIO work?

- People with hemophilia A do not have enough natural coagulation factor VIII in their blood.
- Factor VIII is a protein produced naturally in the body. It helps the blood to form clots to stop bleeding.
- When your body does not produce enough coagulation factor VIII and you become injured, your blood will not form clots and you may bleed into and damage your muscles and joints.
- ALTUVIIIIO is coagulation FVIII made using recombinant technology in a laboratory, which can be given by injection to help control and prevent bleeding in people with hemophilia A.
- ALTUVIIIIO is a factor VIII fusion protein that raises the levels of Factor VIII to help prevent and/or control your bleeding and keeps levels high enough in most instances to require only a once a week injection.

#### What are the ingredients in ALTUVIIIIO?

Medicinal ingredients: Antihemophilic Factor VIII (Recombinant, B-Domain deleted), Fc-VWF-XTEN fusion protein

Non-medicinal ingredients: Arginine hydrochloride, calcium chloride dihydrate, histidine, polysorbate 80 and sucrose

#### ALTUVIIIIO comes in the following dosage forms:

ALTUVIIIIO comes as a powder in a vial. It must be dissolved with the solvent (sterile water) supplied in the pre-filled syringe before use. ALTUVIIIIO is available in 250, 500, 1000, 2000, 3000, and 4000 IU/vial.

#### Do not use ALTUVIIIIO if:

- You are allergic to this drug, or any ingredient listed above (non-medicinal ingredients).
- The expiry date (printed on the vial) has passed. If you take this medicine after the expiry date has passed, it may not work well.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ALTUVIIIIO. Talk about any health conditions or problems you may have including the one's mentioned below:**

#### Allergic Reactions

Allergic reactions, including severe events, are possible. Stop taking ALTUVIIIIO if allergy symptoms occur and contact your doctor and/or seek immediate help.

#### Blood tests

Your doctor will monitor you to make sure ALTUVIIIIO is working well. If your blood levels of FVIII decrease or if bleeding is not controlled after you are given ALTUVIIIIO, this may indicate the presence of an inhibitor (neutralizing antibodies), and you may require a new treatment.

#### Other medicines and products

Tell your doctor, nurse or pharmacist if you are using, have recently used, or might use any other medicines.

#### Pregnancy and/or breastfeeding

- Talk to your doctor before using ALTUVIIIIO if you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby.
- There is no experience with the use of ALTUVIIIIO in pregnant women.
- It is not known whether ALTUVIIIIO passes into human breast milk. Tell your doctor if you are breast-feeding or plan to do so.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

#### **How to take ALTUVIIIIO:**

Medical supervision is recommended the first time ALTUVIIIIO is given, where proper medical care for severe allergic reactions can be provided. You or your caregiver should only take or give ALTUVIIIIO after proper training and only when you feel comfortable to do so.

#### **Usual dose:**

Your doctor will tell you or your caregiver how much ALTUVIIIIO to take or give and how often (usually once a week). You or your caregiver should always follow the specific instructions given by your healthcare professional.

#### **Overdose:**

Tell your doctor immediately.

If you think you, or a person you are caring for, have taken too much ALTUVIIIIO contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

#### **Missed Dose:**

Talk to your doctor if you miss a dose.

## Preparing your dose for administration:

These steps are general guidelines for using ALTUVIIIIO. If you are unsure of these steps, please call your healthcare professional before taking or giving this drug.

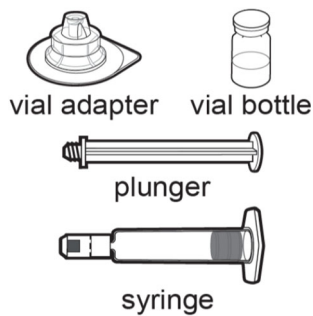
## RECONSTITUTION



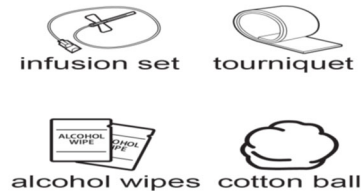
### Step 1:

Look at the product kit:

- Check that you have the correct product and dose with the right colour cap.
- Check the expiration date.
- Do not use the product if the expiration date has passed.



### not included in the carton:

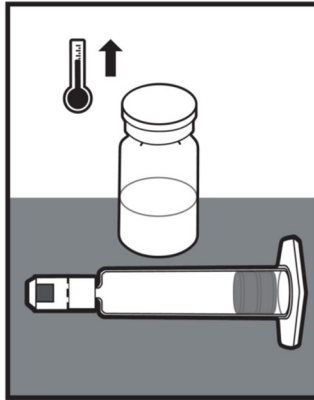


Find a clean, flat work surface. Remove the components from the carton: Vial adapter in its package, Vial with powdered drug, Plunger rod and Prefilled solvent syringe.

Also ensure you have the following supplies (not included in the carton): Infusion set (needle with plastic line), Tourniquet (large elastic band), 2 alcohol wipes, 1 cotton ball or gauze pad, 1 adhesive bandage, 1 tape, 1 larger luer lock syringe (if required; See Step 13) and a puncture-resistant container (See Step 23).

Do not use the product (vial and/or syringe) if it has been dropped on a hard surface or is damaged.

**Step 2:**



Allow the ALTUVIIIIO vial and the syringe with solvent to come to room temperature.

**Do not** heat the vial or syringe with solvent using hot water or other means.

**Do not** put the product into direct sunlight.

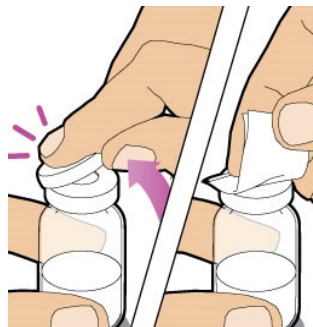
**Do not** return the product to the refrigerator.

**Step 3:**



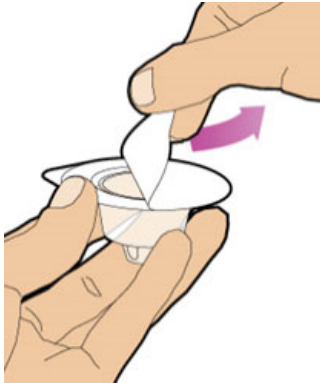
Wash your hands with soap and water.

**Step 4:**



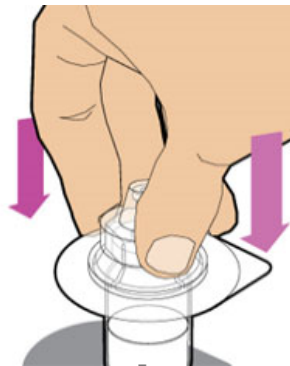
Remove the plastic cap from the ALTUVIIIIO vial. Wipe the rubber stopper of the vial with an alcohol wipe and allow it to dry. After cleaning, **do not** touch the rubber stopper with your hand or allow it to touch any surface.

**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:**

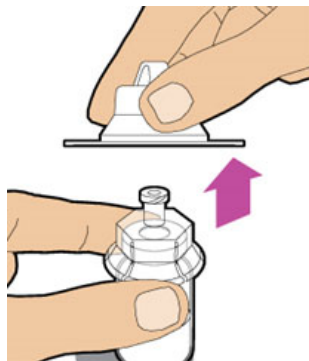


Keep the vial on a flat surface. Hold the vial with one hand and using the other hand, place the vial adapter in its package over the vial.

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

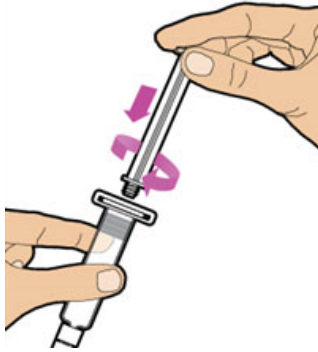
Push the vial adapter straight down until the adapter spike punctures the center of the vial stopper and is fully inserted.

**Step 7:**



Lift the package cover away from the vial adapter and discard the cover and keep on a flat surface until Step 11.

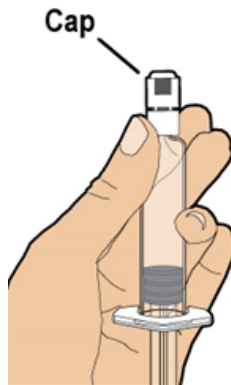
**Step 8:**



*Note: Only use the syringe with solvent provided to dissolve the drug product.*

Hold the plunger rod at the circular disk (top hand in picture). Place the tip of the plunger rod into the end of the syringe. Turn the plunger rod in a clockwise (left to right) motion until it is firmly attached.

**Step 9:**

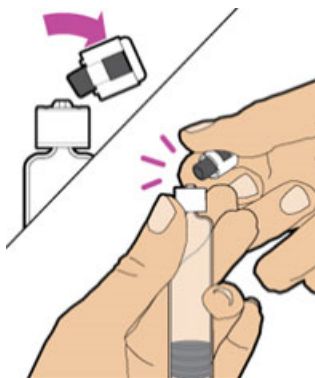


With one hand, hold the syringe with solvent right under the cap, and with the cap pointing up.

*Note: Make sure you are holding the 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:**

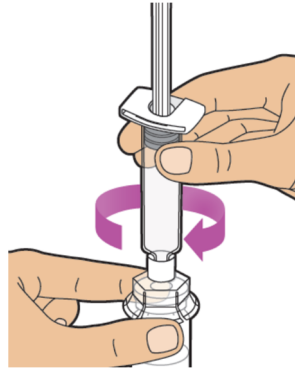


With your other hand, grasp the cap and bend it at a ninety-degree (90°) angle until it snaps off.

*Note: 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.

**Step 11:**

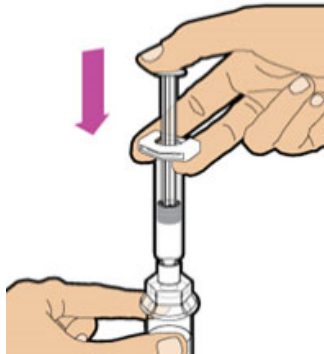


*Note: Be sure the vial is sitting on a flat surface.*

Turn the syringe over and insert the tip of the syringe into the vial adapter opening.

Turn the syringe in a clockwise (left to right) motion until it is securely attached to the vial adapter.

**Step 12:**



Slowly push the plunger rod down to inject all of the solvent from the syringe into the vial.

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

**Step 13:**



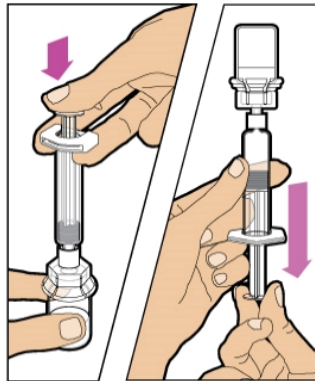
With the syringe still connected to the adapter, gently swirl the vial until the product is completely dissolved. Check the solution through the vial to make sure the powder is fully dissolved.

*Note: The appearance of the solution should look clear and colourless. Your doctor will show you how the drug should look.*

**Do not** shake. **Do not** use the ALTUVIIIIO in solution if it contains visible particles or is cloudy. Check the solution through the vial to make sure the powder is fully dissolved.

**POOLING:** This is the process of combining two or more vials with the drug already in solvent into a larger syringe (not included in the carton and not pictured). If the dose requires more than one vial, combine each vial as described above (See Steps 4 – 13) with the syringe provided. **Keep** the syringe attached until you are ready to add the larger luer lock syringe to the next vial. Use a larger luer lock plastic syringe to combine the contents of the reconstituted vials into the syringe, similar as described in the Steps 14-15. Repeat this pooling procedure with each vial you will be using. Once you have pooled the required dose, proceed with the Step 16 (administration) using the larger syringe. Your healthcare professional will show you or your caregiver how to combine two or more vials into a larger syringe.

**Step 14:**

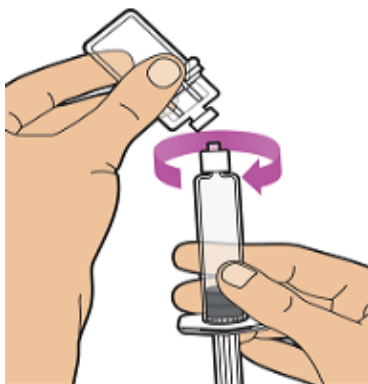


*Note: Be careful not to pull the plunger rod completely out of the syringe.*

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



### Step 15



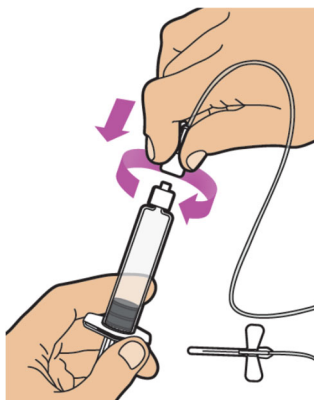
Gently unscrew the syringe from the vial adapter using a clockwise motion. Dispose of the vial with the adapter still attached. If you are not ready to inject, put the syringe cap carefully back onto the syringe tip. **Do not** touch the syringe tip or the inside of the cap.

*Note: ALTUVIIIIO should be administered within 3 hours after it is in solution.*

### ADMINISTRATION

ALTUVIIIIO is given by intravenous infusion after the drug powder is in solvent. These are general instructions so your healthcare professional can teach you or your caregiver how to inject ALTUVIIIIO. Once you or your caregiver have been taught to give ALTUVIIIIO, you can follow these instructions. Do not give if the product in solution contains particles, is discoloured, or is cloudy.

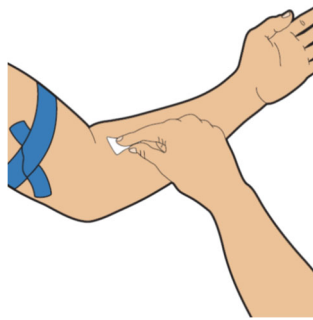
### Step 16:



With clean hands in a clean area, attach the syringe to the connector end of the infusion set tubing by turning clockwise (left to right) until it is securely attached. **Do not** mix ALTUVIIIIO in the same tubing or container with other drugs.

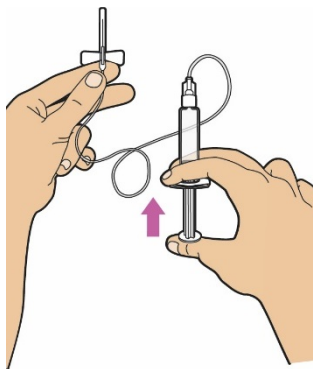
*Note: Ask your healthcare professional which infusion set can be used for this product.*

**Step 17:**



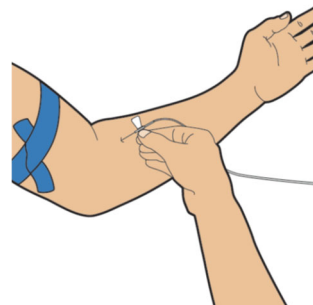
Apply a tourniquet (large elastic band) to the upper arm as trained. Then, using a new alcohol wipe, clean the skin area where you will insert the needle and wait for it to dry.

**Step 18:**



Fill the syringe and the tubing by pushing gently on the plunger rod until all air is removed from the syringe and ALTUVIIIIO has just filled the needle. **Do not** push ALTUVIIIIO through the needle.

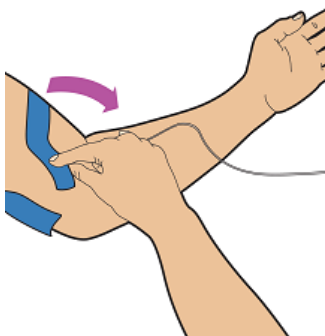
**Step 19:**



Remove the protective needle cover from the infusion set needle and discard it. **Do not** touch the needle (hold by plastic arms) 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 professional. Ensure that tape is ready to secure the plastic wings of the needle later on.

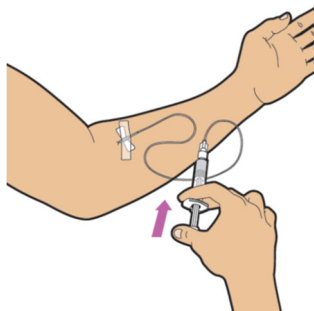
**Step 20:**



Remove the tourniquet. Use a tape to secure the plastic wings of the needle in place at the injection site if necessary (as shown in Step 21 below).

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

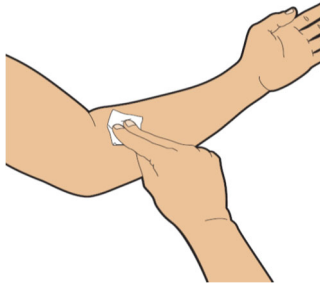
**Step 21:**



Slowly push the plunger rod on the syringe down to give ALTUVIIIIO into the vein. Your healthcare professional will tell you or your care giver how fast to give ALTUVIIIIO based on your comfort level. The time to give ALTUVIIIIO will depend on how hard you or your caregiver pushes on the plunger and this may take practice under supervision.

*Note: A small amount of drug product will be left in the infusion set after infusion. This is normal.*

**Step 22:**



After ALTUVIIIIO is given, 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 possible bleeding.

*Note: You may apply an adhesive bandage if necessary.*

**Step 23:**



Put the infusion set, the syringe and cap, the used vial, and other used medical supplies in a puncture-resistant container right away after use. **Do not** dispose of (throw away) ALTUVIIIIO in your household trash.

**What are possible side effects from using ALTUVIIIIO?**

You can have an allergic reaction to ALTUVIIIIO. Call your healthcare professional or emergency department right away if you have any of the following symptoms: difficulty breathing, chest tightness, swelling of the face, rash or hives. Your body can also make antibodies called “inhibitors” against ALTUVIIIIO. This can stop ALTUVIIIIO from working properly. Your healthcare professional may give you blood tests to check for inhibitors.

The common side effects of ALTUVIIIIO are headache, joint pain, and back pain. These are not the only possible side effects of ALTUVIIIIO. Tell your healthcare professional about any side effect that bothers you or does not go away.

If you experience any of those side effects, seek immediate medical attention.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
The following side effects could mean you are having an allergic reaction.			
Difficulty breathing			√
Chest tightness			√
Swelling of the face, rash or hives			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

#### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

#### Storage:

Do not use product or solvent after the expiry date that is shown on the label of the vial and the carton. Unopened vials should be stored under controlled refrigeration (2°C - 8°C). The product as a powder 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.

Do not use beyond the expiration date printed on the carton and the vial or six months after removing the carton from refrigeration, whichever is earlier.

Do not freeze. Protect from light.

The dissolved product can be stored at room temperature up to 30°C for 3 hours. Protect product from direct sunlight. After adding the solvent, if the product is not used within 3 hours, it must be thrown away.

The appearance of the dissolved product should be clear and colourless.

Do not use this medicine if you notice that it is cloudy or contains visible particles.

**If you want more information about ALTUVIIIIO:**

- Talk to your healthcare professional.
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website [www.sanofi.com/en/canada](http://www.sanofi.com/en/canada), or by calling 1-800-265-7927.

This leaflet was prepared by sanofi-aventis Canada Inc.

Last Revised: March 26, 2025

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