PART III: CONSUMER INFORMATION

ALPROLIX® [pronounced all' prō liks]
Coagulation Factor IX (Recombinant), Fc Fusion Protein

This leaflet is part III of a three-part "Product Monograph" published when ALPROLIX was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ALPROLIX. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

- ALPROLIX is used to help control and prevent bleeding in people with hemophilia B. Hemophilia B is also called congenital factor IX deficiency or Christmas disease.

What it does:

- ALPROLIX is coagulation Factor IX made in the laboratory using recombinant technology. It can be used to help people with Hemophilia B who do not have enough natural coagulation factor IX in their blood to form clots.

When it should not be used:

Do not use ALPROLIX if you:

- Have an allergy or are sensitive to ALPROLIX or any ingredients listed below.

If you are not sure if you should use ALPROLIX, talk to your doctor.

What the medicinal ingredient is:

Coagulation Factor IX (Recombinant), Fc Fusion Protein

What the nonmedicinal ingredients are:

When reconstituted with provided diluent, the product contains L-histidine, mannitol, polysorbate 20, sodium chloride and sucrose.

What dosage forms it comes in:

Powder in a vial.
Available nominally in 250, 500, 1000, 2000, 3000 and 4000 IU/vial.

Before use, the powder in the vial must be mixed with the liquid in the pre-filled syringe. After mixing, the actual activity level is printed in International Units on the label. The product contains approximately 50, 100, 200, 400, 600 and 800 IU/mL.

WARNINGS AND PRECAUTIONS

BEFORE you use ALPROLIX talk to your doctor or hemophilia treatment centre about all of your medical conditions, including if you:

- Are pregnant or planning to become pregnant. It is not known if ALPROLIX may harm your unborn baby.
- Are breastfeeding. It is not known if ALPROLIX passes into the milk and if it can harm your baby.
- Have any allergies to this drug or its ingredients or components of the container (see When it should not be used).

Allergic reactions may occur with ALPROLIX. Call your doctor or get emergency treatment right away if you have any of the following symptoms:

- Difficulty breathing
- Chest tightness
- Swelling of the face
- Rash
- Hives

ALPROLIX may increase the risk of formation of abnormal blood clots in your body if you have risk factors for developing blood clots.

Your body can also make antibodies called "inhibitors" against ALPROLIX, which may stop ALPROLIX from working properly.

INTERACTIONS WITH THIS MEDICATION

You should tell your doctor(s) if you are taking any other prescription or non-prescription medicines. This includes vitamin or mineral supplements, herbal products or natural health products.

PROPER USE OF THIS MEDICATION

Always follow your doctor's instructions for taking ALPROLIX. The first time you inject ALPROLIX, you should be under proper medical supervision, where proper medical care for severe allergic reactions could be provided.

Usual dose:
Your doctor will prescribe the dose you should take. The steps in Preparing Your Dose for Administration are general guidelines for using ALPROLIX. If you are unsure of these procedures, please call your healthcare provider before using.

Overdose:
No symptoms of overdose have been reported.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even though you may not feel sick.

Missed Dose:
Use your dose of ALPROLIX as soon as you remember and then resume your normal dosing schedule.

Do not use a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Allergic reactions may occur with ALPROLIX (see Warnings and Precautions).

Some common side effects of ALPROLIX are headache, abnormal sensation in the mouth and obstructive uropathy (pain in your side with blood in your urine).

ALPROLIX may increase the risk of formation of abnormal blood clots in your body if you have risk factors for developing blood clots.

Your body can also make antibodies called 'inhibitors' against ALPROLIX. These inhibitors may stop ALPROLIX from working properly. Tell your doctor if you are using increasing amounts of ALPROLIX to control or prevent bleeding.

Talk to your doctor about any side effect that bothers you or that does not go away.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM	
Symptom / effect	**Stop taking ALPROLIX and call your doctor immediately**
The following side effects could mean you are having an allergic reaction.	
Difficult breathing	√
Chest tightness	√
Swelling of the face, rash or hives	√

This is not a complete list of side effects. For any unexpected effects while taking ALPROLIX, contact your doctor or pharmacist.

PREPARING YOUR DOSE FOR ADMINISTRATION

Read all the instructions before you start. There are 5 steps, explained in this guide.

A. Setting Up
B. Reconstituting the injection
C. Pooling
D. Giving the injection
E. Post-Injection Care and Disposal

A. Setting Up

Ensure that your work area is clean.
Collect everything you will need. Wash your hands thoroughly with soap and water before performing the following procedures.

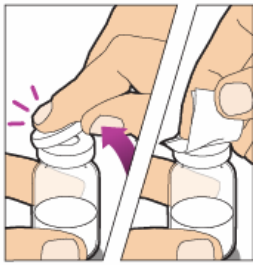
Check the expiry date on the ALPROLIX package. If it is out of date, do not use it and contact your clinic immediately. Obtain a replacement package. If refrigerated, allow the vial of ALPROLIX and pre-filled diluent syringe to reach room temperature before use.

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

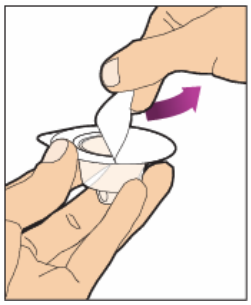
Use the diluent in the pre-filled syringe supplied in the package.

Actual factor IX activity in International Units is stated on the label of each ALPROLIX carton and vial.

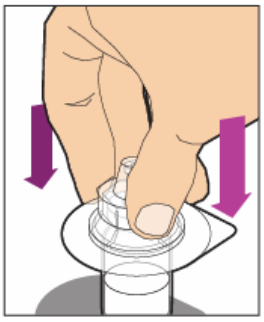
Remove the plastic cap from the ALPROLIX vial and wipe the rubber stopper of the vial with an alcohol wipe. Allow the rubber stopper to dry. After cleaning, do not touch the rubber stopper with your hand or allow it to touch any surface.



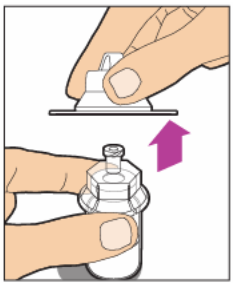
Completely remove the backing from the vial adapter package by peeling back the lid. Do not remove the vial adapter from the package or touch the inside of the package of the adapter.



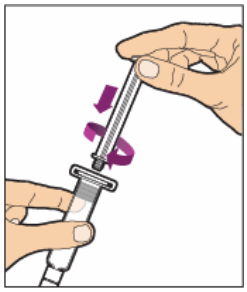
Keep the vial on a flat surface. Hold the vial adapter package with one hand and using the other hand, place the vial adapter over the vial. Place the adapter spike directly above the centre of the rubber stopper. Push the vial adapter straight down until the adapter spike punctures the centre of the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



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

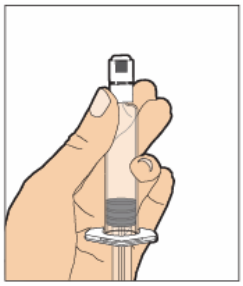


Take the plunger rod and syringe out of the package. Hold the plunger rod at the circular disk. Place the tip of the plunger rod into the end of the syringe. Turn clockwise until it is securely attached. Only use the diluent syringe provided in the ALPROLIX package.

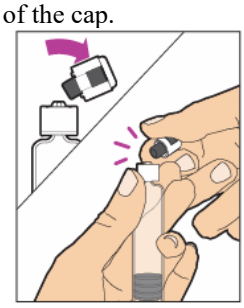


B. Reconstituting the injection

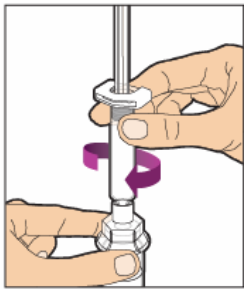
With one hand, hold the diluent syringe by the ridged part right under the cap, with the cap pointing up. Do not use if the cap has been removed or is not securely attached.



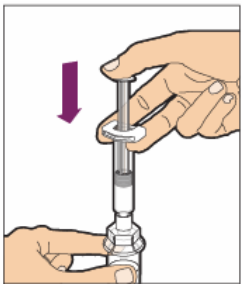
With your other hand, grasp the cap and bend it at a 90° angle until it snaps off. After the cap snaps off, you will see the glass tip of the syringe. Do not touch the glass tip of the syringe or inside of the cap.



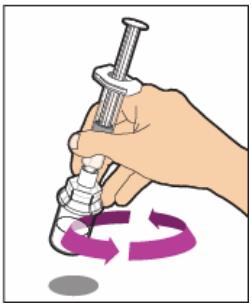
Be sure the vial is sitting on a flat surface. Insert the tip of the syringe into the adapter opening. Turn the syringe clockwise until it is securely attached to the adapter.



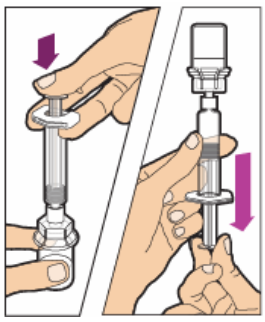
Slowly depress the plunger rod to inject all of the diluent into the vial. The plunger rod may rise slightly after this process. This is normal.



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

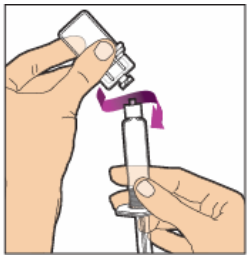


Make sure the plunger rod is completely depressed. Turn the vial upside-down. Slowly pull on the plunger rod to draw the solution into the syringe. Be careful not to pull the plunger rod completely out of the syringe.



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.

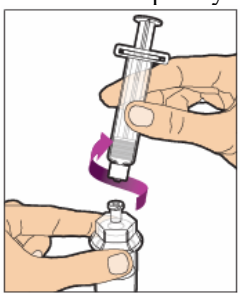
Your ALPROLIX is now ready to be connected to your infusion tubing set. See section D. Use the reconstituted ALPROLIX as soon as possible, but no later than 3 hours after reconstitution. Protect from direct sunlight. **Do not refrigerate after reconstitution.**



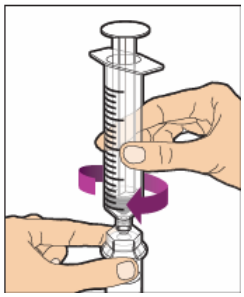
C. Pooling

If you are using two or more vials of ALPROLIX, you can 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).

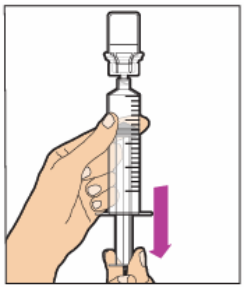
Remove the diluent syringe from the vial adapter by turning it counterclockwise until it is completely detached.



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



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.

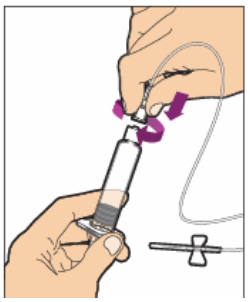


D. Giving the injection
For Intravenous Injection only after Reconstitution

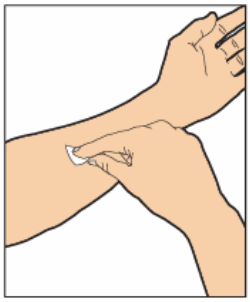
Inspect the reconstituted ALPROLIX solution visually for particulate matter and discolouration prior to administration. Do not use if particulate matter or discolouration is observed.

Do not administer reconstituted ALPROLIX in the same tubing or container with other medications.

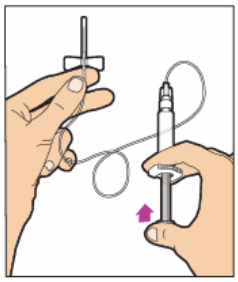
Attach the syringe to the connector end of the infusion set tubing by turning clockwise until it is securely attached. Do not remove the protective needle cover until you are ready to insert the needle.



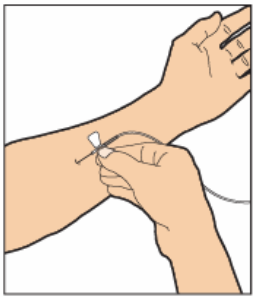
Apply a tourniquet and clean the skin area where you will perform the injection using an alcohol wipe.



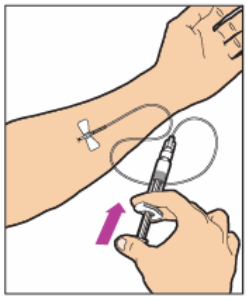
Depress the plunger until all air is removed from the syringe and ALPROLIX has reached the end of the infusion set tubing. Do not push ALPROLIX through the needle.



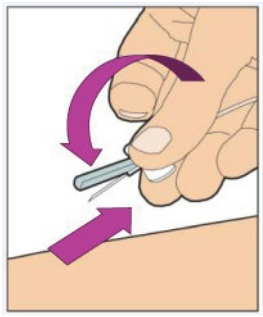
Remove the protective needle cover from the infusion set tubing. Insert the needle on the infusion set tubing into the vein. Remove the tourniquet. Always verify proper needle placement when performing intravenous administration.



Slowly depress the plunger on the syringe to administer ALPROLIX. ALPROLIX 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.

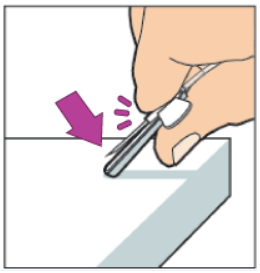


After infusing ALPROLIX, flip the safety shield towards the needle. Remove the infusion set.

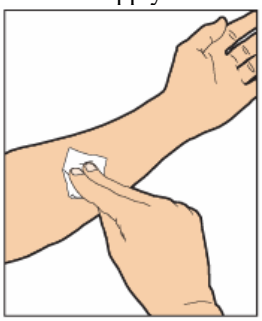


Post-Injection Care and Disposal

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.



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



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

HOW TO STORE IT

Keep the vials of ALPROLIX in the refrigerator at 2°C to 8°C.

You can keep the vials of ALPROLIX at room temperature at 15°C to 30°C for a single 6-month period.

Write the date that you take the product out of the refrigerator on the carton to help you remember. You must either use the product or dispose of it before the end of this 6-month period.

Do not freeze the product otherwise the pre-filled diluent syringe may be damaged.

Protect the ALPROLIX vials from light.

After reconstitution, you can keep the product at room temperature at 15°C to 30°C for three (3) hours. Protect from direct sunlight. If you do not use the product within 3 hours, you must not use it. Do not use ALPROLIX if the reconstituted solution is not clear to slightly opalescent and colourless.

Throw away any unused ALPROLIX.

Do not use product or diluent after the expiry date that is shown on the label of the vial and the carton.

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 (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) 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.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained by contacting the manufacturer's website www.sanofi.ca, or by calling 1-800-265-7927.

This leaflet was prepared by sanofi-aventis Canada Inc.

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