PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
ESPEROCT®
Antihemophilic Factor FVIII (Recombinant, B-Domain Truncated), PEGylated

Read this carefully before you start taking ESPEROCT® 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 ESPEROCT®.

What is ESPEROCT® used for?
ESPEROCT® is a long-acting recombinant coagulation Factor VIII product. Factor VIII is a protein found in the blood that helps to prevent and stop bleeding.

ESPEROCT® is used to treat and prevent bleeding in people with hemophilia A.

How does ESPEROCT® work?
In people with hemophilia A, Factor VIII is missing or does not work properly. ESPEROCT® replaces this faulty or missing Factor VIII and helps blood to form clots at the site of bleeding.

What are the ingredients in ESPEROCT®?
Medicinal ingredients: Antihemophilic Factor VIII (Recombinant, B-Domain Truncated), PEGylated

Non-medicinal ingredients: Calcium chloride dihydrate, L-Histidine, L-Methionine, polysorbate 80, sodium chloride, sucrose

ESPEROCT® comes in the following dosage forms:
ESPEROCT® is available in single-dose vials that contain nominally 500, 1000, 1500, 2000 or 3000 International Units (IU). After reconstitution with the supplied solvent (0.9% sodium chloride solution for injection), the prepared solution for injection will have the following concentration:

Vial Size	Approximate concentration after reconstitution
500 IU	125 IU/mL
1000 IU	250 IU/mL
1500 IU	375 IU/mL
2000 IU	500 IU/mL
3000 IU	750 IU/mL

Each pack of ESPEROCT® contains a vial with white to off-white powder, a 4 mL prefilled syringe with a clear colourless solvent, a plunger rod, and a vial adapter.

Do not use ESPEROCT® if:
You are allergic to the medicinal ingredient, or to any ingredient in the formulation (including hamster protein), or component of the container.

To help avoid side effects and ensure proper use, talk to your healthcare professional

before you take ESPEROCT®. Talk about any health conditions or problems you may have, including if you:

- Are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription or herbal medicines.
- Are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Other warnings you should know about:

Previous use of Factor VIII medicine
Tell your doctor if you have used Factor VIII medicines before that have not worked well as this could happen with ESPEROCT®.

Allergic reactions (hypersensitivity)
There is a risk that you may experience a severe and sudden allergic reaction (e.g. anaphylactic reaction) to ESPEROCT®.

Stop the injection and contact your doctor or an emergency unit immediately if you have early signs of allergic reactions (see Serious Side Effects table).

Medicine Stops Working
A response from your immune system might occur in the beginning of your treatment, or if you switch to ESPEROCT® from another FVIII therapy, which could make this medicine work less well or not at all. Tell your doctor immediately if your bleeding is not controlled with ESPEROCT®. You may require a different therapy if this happens.

Catheter-related problems
If you have a catheter where medicines can be injected into your blood (central venous access device), you may develop infections or blood clots at the site of the catheter.

ESPEROCT® contains sodium
This medicine contains 72 mg of sodium chloride (18 mg/mL) after it has been reconstituted. Talk to your doctor if you are on a controlled sodium diet.

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

The following may interact with ESPEROCT®:
There are no known interactions of ESPEROCT® with other medicinal products.

How to take ESPEROCT®:
Treatment with ESPEROCT® will be started by a doctor who is experienced in the care of people with hemophilia A. Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure about how to use ESPEROCT®.

ESPEROCT® is given as an injection into a vein (intravenously). Please refer to the end of this insert for instructions on how to prepare and administer ESPEROCT®.

Your doctor will calculate your dose for you. This will depend on your body weight and whether it is used to prevent or to treat a bleeding.

Usual dose:
Prevention of bleeding

- **Adults and adolescents** (children 12 years of age and above): The recommended dose is 50 IU of ESPEROCT® per kg body weight every 4 days.

- **Children** (below 12 years of age): The recommended dose is 50–75 IU of ESPEROCT® per kg of body weight. This is given twice weekly.

Treatment of bleeding
The dose of ESPEROCT® is calculated based on your body weight, the severity of your hemophilia A, and the location of the bleeding. If you experience that the effect of ESPEROCT® is insufficient, talk to your doctor.

Use in children and adolescents
ESPEROCT® can be used in children of all ages. In children (below 12 years of age) higher doses or more regular injections may be needed. Adolescents (children 12 years of age and above) can use the same dose as adults.

Overdose:

If you think you have taken too much ESPEROCT®, contact your healthcare professional, your hemophilia treatment centre or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:
If you forget a dose, inject the missed dose as soon as you remember. Do not inject a double dose to make up for a forgotten dose. Proceed with the next injection as scheduled and continue as advised by your doctor. If you are in doubt, contact your doctor.

Stopping Treatment:
Do not stop using ESPEROCT® without talking to your doctor.

If you stop using ESPEROCT®, you may no longer be protected against bleeding or a current bleed may not stop. If you have any further questions on the use of this medicine, ask your doctor.

What are possible side effects from using ESPEROCT®?

These are not all the possible side effects you may feel when taking ESPEROCT®. If you experience any side effects not listed here, contact your healthcare professional.

The following side effects have been observed with ESPEROCT®:

Very common side effects (may affect more than 1 in 10 people)
- For previously untreated patients the medicine stops working or doesn't work as well (factor VIII inhibition)

Common side effects (may affect up to 1 in 10 people)
- Skin reactions where the injection is given

- Itching (pruritus)
- Redness of skin (erythema)
- Rash
- Allergic reactions: (hypersensitivity) for patients not previously treated with factor VIII. These may become severe and could be life threatening, see “Allergic reactions (hypersensitivity) above for more information.

Uncommon side effects (may affect up to 1 in 100 people)

- Allergic reactions (hypersensitivity) for patients previously treated with factor VIII. These may become severe and could be life-threatening (see Serious Side Effects table).
- Medicine stops working due to an immune response (antibodies) against ESPEROCT®.

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**	
UNCOMMON			
Lack of effect: Bleeding does not stop after taking ESPEROCT®		✓	
Allergic reaction: Difficulty in swallowing or breathing; shortness of breath or wheezing; chest tightness; redness and/or swelling of the lips, tongue, face or hands; rash, hives, weals or generalized itching; pale and cold skin, fast heartbeat, or dizziness (low blood pressure)		✓	✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to 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:
Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, on the vial, and on the prefilled syringe labels. The expiry date refers to the last day of that month.

The powder in the vial appears as a white to off-white powder. Do not use the powder if the colour has changed.

Prior to reconstitution

Before mixing the powder in the vial with the solvent:

Store in the original package in order to protect from light. Do not freeze.

ESPEROCT® vials can be stored in the refrigerator (2°C – 8°C) up to the expiration date. During the shelf life, the product may also be kept at room temperature up to 30°C for a single period no longer than 12 months, **or** up to 40°C for a single period no longer than 3 months.

If you choose to store ESPEROCT® at room temperature:

- Note the date that the product is removed from refrigeration on the carton.
- Do not use after 12 months if stored up to 30°C **or** after 3 months if stored up to 40°C **or** after the expiration date listed on the carton, whichever occurs earlier.
- Do not return the product to the refrigerator after it has been stored at room temperature.

After reconstitution

After the powder is mixed with the solvent:

Once you have reconstituted ESPEROCT®, it should be used immediately. If you cannot use the reconstituted solution immediately, it must be used within 24 hours when stored in the refrigerator at 2°C - 8°C, within 4 hours when stored at room temperature up to 30°C, or within 2 hours when stored between 30°C and 40°C. Store the reconstituted product in the vial, with the vial adapter and the syringe still attached.

Keep reconstituted ESPEROCT® solution out of direct light.

The reconstituted solution must be clear and colourless. Do not use the reconstituted solution if you notice any particles or discolouration.

If you want more information about ESPEROCT®:

- 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 http://www.novonordisk.ca, or by calling 1-800-465-4334.

This leaflet was prepared by Novo Nordisk Canada Inc.

Last Revised: September 11, 2023

INSTRUCTIONS ON HOW TO USE ESPEROCT®

READ THESE INSTRUCTIONS CAREFULLY BEFORE USING ESPEROCT®.

ESPEROCT® is supplied as a powder. Before injection, it must be reconstituted with the solvent supplied in the syringe. The solvent is a 0.9% sodium chloride solution. The reconstituted ESPEROCT® must be injected into your vein (intravenous [i.v.] injection). The equipment in this package is designed to reconstitute and inject ESPEROCT®.

You will also need:
- an infusion set (butterfly needle with tubing)
- sterile alcohol swabs
- gauze pads and plasters

These items are not included in the ESPEROCT® package.

Do not use the equipment without proper training from your doctor or nurse.

Always wash your hands and ensure that the area around you is clean.

When you prepare and inject medicine directly into a vein, it is important to **use a clean and germ free (aseptic) technique.** An incorrect technique can introduce germs that can infect your blood.

Do not open the equipment until you are ready to use it.

Do not use the equipment if it has been dropped, or if it is damaged. Use a new package instead.

Do not use the equipment if it has expired. Use a new package instead. The expiry date is printed on the outer carton, on the vial, on the vial adapter, and on the prefilled syringe.

Do not use the equipment if you suspect it is contaminated. Use a new package instead.

Do not dispose of any of the items until after you have injected the reconstituted solution.

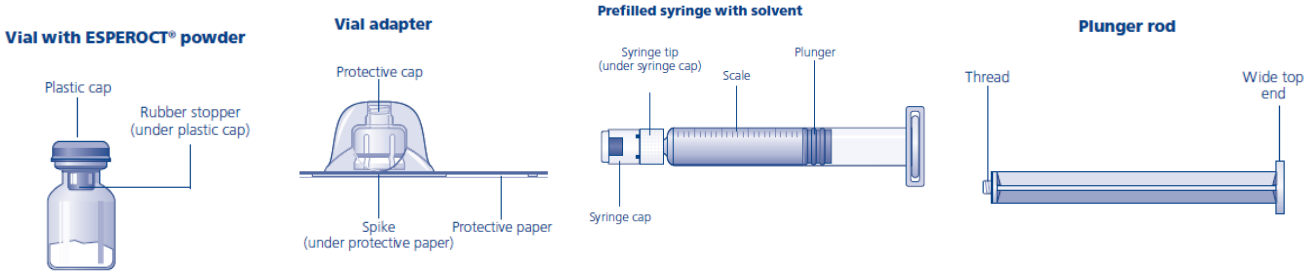
The equipment is for single use only.

Contents

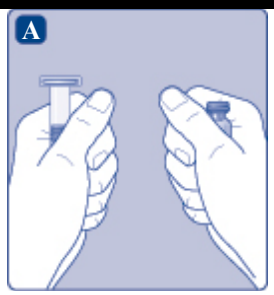
The package contains:
- 1 vial with ESPEROCT® powder
- 1 vial adapter
- 1 prefilled syringe with solvent
- 1 plunger rod (placed under the syringe)

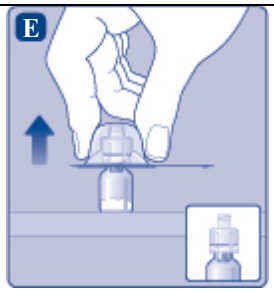
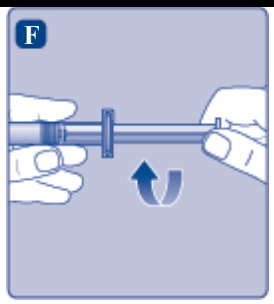
The prefilled solvent syringe with sterile vial adapter, together serve as a needleless reconstitution system named the MixPro®.

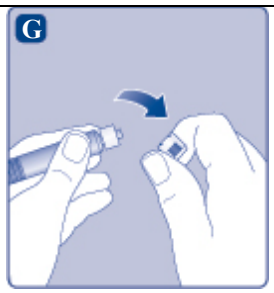
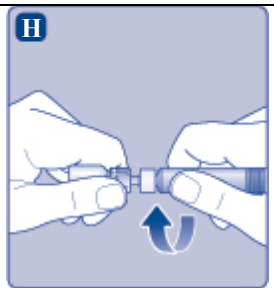
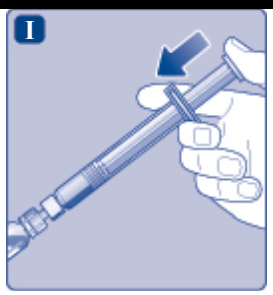
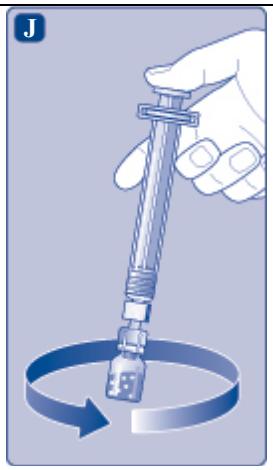
Overview



1. Prepare the Vial and Syringe

Step A		**Take out the number of ESPEROCT® packages you need.** **Check the expiry date.** **Check the name, strength and colour** of the package to make sure it contains the correct product. **Wash your hands** and dry them properly using a clean towel or let them air dry. Take the vial, the vial adapter and the prefilled syringe out of the carton. **Leave the plunger rod untouched in the carton.** **Bring the vial and the prefilled syringe to room temperature.** You can do this by holding them in your hands until they feel as warm as your hands. **Do not use any other way to warm** the vial and prefilled syringe.
Step B		**Remove the plastic cap** from the vial. **If the plastic cap is loose or missing, do not use the vial.** **Wipe the rubber stopper with a sterile alcohol swab** and allow it to air dry for a few seconds before use to ensure that it is as germ free as possible. **Do not touch the rubber stopper with your fingers as this can transfer germs.**

2. Attach the Vial Adapter		
Step C		**Remove the protective paper from the vial adapter.** **If the protective paper is not fully sealed or if it is broken, do not use the vial adapter.** **Do not take the vial adapter out of the protective cap with your fingers.** If you touch the spike on the vial adapter, germs from your fingers can be transferred.
Step D		**Place the vial on a flat and solid surface.** **Turn over the protective cap,** and snap the vial adapter onto the vial. **Once attached, do not remove the vial adapter from the vial.**
Step E		Lightly **squeeze the protective cap** with your thumb and index finger as shown. **Remove the protective cap** from the vial adapter. **Do not lift the vial adapter from the vial** when removing the protective cap.
3. Attach the Plunger Rod and the Syringe		
Step F		Grasp the plunger rod by the wide top end and take it out of the carton. **Do not touch the sides or the thread of the plunger rod.** If you touch the sides or the thread, germs from your fingers can be transferred**.** **Immediately** connect the plunger rod to the syringe by turning it clockwise into the plunger inside the prefilled syringe until resistance is felt.

Step G		**Remove the syringe cap** from the prefilled syringe by bending it down until the perforation breaks. **Do not touch the syringe tip under the syringe cap.** If you touch the syringe tip, germs from your fingers can be transferred. **If the syringe cap is loose or missing, do not use the prefilled syringe.**
Step H		**Screw the prefilled syringe securely** onto the vial adapter until resistance is felt.
4. Reconstitute the Powder with the Solvent		
Step I		**Hold the prefilled syringe slightly tilted** with the vial pointing downwards. **Push the plunger rod** to inject all the solvent into the vial.
Step J		**Keep the plunger rod pressed down and swirl** the vial gently until all the powder is dissolved. **Do not shake the vial as this will cause foaming.** **Check the reconstituted solution.** It must be clear and colourless and no particles should be visible. **If you notice particles or discolouration, do not use it.** Use a new package instead.

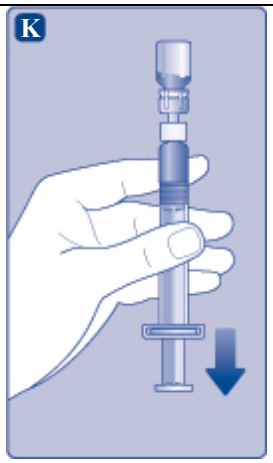
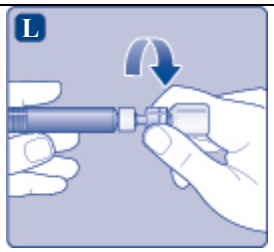
ESPEROCT® is recommended to be used immediately after it has been reconstituted.

If you cannot use the reconstituted ESPEROCT® solution immediately, it must be used within 24 hours when stored in the refrigerator at 2°C - 8°C, within 4 hours when stored at room temperature up to 30°C, or within 2 hours when stored between 30°C and 40°C. Store the reconstituted product in the vial, with the vial adapter and the syringe still attached.

Do not freeze reconstituted ESPEROCT® solution or store it in syringes.

Keep reconstituted ESPEROCT® solution out of direct light.

If your dose requires more than one vial, repeat step **A** to **J** with additional vials, vial adapters and prefilled syringes until you have reached your required dose.

Step K		**Keep the plunger rod pushed completely in.** **Turn the syringe with the vial** upside down. **Stop pushing the plunger rod and let it move back** on its own while the reconstituted solution fills the syringe. **Pull the plunger rod slightly downwards** to draw the reconstituted solution into the syringe. **If you do not need to use all of the reconstituted medicine from the vial,** use the scale on the syringe to withdraw the dose you need, as instructed by your doctor or nurse. If, at any point, there is air in the syringe, inject the air back into the vial. While holding the vial upside down, **tap the syringe gently** to let any air bubbles rise to the top. **Push the plunger rod** slowly until all air bubbles are gone.
Step L		**Unscrew the vial adapter** with the vial. **Do not touch the syringe tip.** If you touch the syringe tip, germs from your fingers can be transferred.

5. Inject the Reconstituted Solution

ESPEROCT® is now ready to be injected into your vein.

- Inject the reconstituted solution as instructed by your doctor or nurse.
- Inject slowly over approximately 2 minutes.
- Do not mix ESPEROCT® with any other intravenous injections or medications.

Injecting ESPEROCT® via needleless connectors for intravenous (IV) catheters

Caution: The MixPro® prefilled solvent syringe is made of glass and is designed to be compatible with standard luer-lock connections. Some needleless connectors with an internal spike are incompatible with the prefilled syringe. This incompatibility may prevent administration of the drug and result in damage to the needleless connector.

Injecting the solution via a central venous access device (CVAD) such as a central venous catheter or a subcutaneous port:

- Use a clean and germ free (aseptic) technique. Follow the instructions for proper use for your connector and CVAD in consultation with your doctor or nurse.
- Injecting into a CVAD may require using a sterile 10 mL plastic syringe for withdrawal of the reconstituted solution. This should be done right after step **J**.
- If the CVAD line needs to be flushed before or after the injection of ESPEROCT®, use 0.9% Sodium Chloride solution for injection.

If you have encountered any problems with attaching the prefilled solvent syringe to any luer-lock compatible device, or have any questions please contact Novo Nordisk at 1-800-465-4334.

6. Disposal

Step M		**After injection, safely dispose** of all unused ESPEROCT® solution, the syringe with the infusion set, the vial with the vial adapter, and other waste materials as instructed by your healthcare provider. Do not throw it out with the ordinary household waste.

Do not disassemble the equipment before disposal.

Do not reuse the equipment.