Package leaflet: Information for the user

Esperoct 500 IU powder and solvent for solution for injection
Esperoct 1000 IU powder and solvent for solution for injection
Esperoct 1500 IU powder and solvent for solution for injection
Esperoct 2000 IU powder and solvent for solution for injection
Esperoct 3000 IU powder and solvent for solution for injection
Esperoct 4000 IU powder and solvent for solution for injection
Esperoct 5000 IU powder and solvent for solution for injection

turoctocog alfa pegol (pegylated human coagulation factor VIII (rDNA))

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
– Keep this leaflet. You may need to read it again.
– If you have any further questions, ask your doctor.
– This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
– If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Esperoct is and what it is used for

What Esperoct is
Esperoct contains the active substance turoctocog alfa pegol and 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.

What Esperoct is used for
Esperoct is used to treat and prevent bleeding in people of all age groups with haemophilia A (inborn factor VIII deficiency).

In people with haemophilia 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.

2. What you need to know before you use Esperoct

Do not use Esperoct
- if you are allergic to the turoctocog alfa pegol or to any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to hamster proteins.

Do not use Esperoct if either of the above applies to you. If you are not sure, talk to your doctor before using this medicine.

Warnings and precautions

Previous use of factor VIII medicine
Tell your doctor if you have used factor VIII medicines before, especially if you developed inhibitors (antibodies) against the medicine, since there might be a risk that it happens again.

Allergic reactions
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. These early signs may include rash, hives, weals, itching on large areas of skin, redness and/or swelling of lips, tongue, face or hands, difficulty in swallowing or breathing, wheezing, tightness of the chest, pale and cold skin, fast heartbeat, or dizziness, headache, nausea and vomiting.

Development of 'factor VIII inhibitors' (antibodies)
Inhibitors (antibodies) can develop during the treatment with all factor VIII medicines
- These inhibitors, especially at high levels, stop the treatment working properly
- You will be monitored carefully for development of these inhibitors
- If your bleeding is not being controlled with Esperoct, tell your doctor immediately
- Do not increase the total dose of Esperoct to control your bleed without talking to your doctor.

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.

Heart disease
Talk to your doctor or pharmacist if you have heart disease or you are at risk of heart disease.

Other medicines and Esperoct
Tell your doctor if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding
If you 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.

Driving and using machines
Esperoct has no influence on your ability to drive and use machines.

Decreased factor VIII activity in previously untreated patients
A decreased factor VIII activity may occur in the beginning of the treatment. If a bleeding is not being controlled with Esperoct, talk to the treating doctor immediately.

Decreased factor VIII activity in previously treated patients
A decreased factor VIII activity may occur in the beginning of your treatment. Talk to your doctor if your bleeding is not being controlled with your usual dose of Esperoct.

Esperoct contains sodium
This medicine contains 30.5 mg sodium (main component of cooking/table salt) per reconstituted vial. This is equivalent to 1.5% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Esperoct

Treatment with Esperoct will be started by a doctor who is experienced in the care of people with haemophilia 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.

How Esperoct is given
Esperoct is given as an injection into a vein (intravenously), see "Instructions on how to use Esperoct" for more information.

How much to use
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.

To prevent bleeding
For children (below 12 years of age), the recommended dose is 65 IU of Esperoct per kg body weight twice weekly. Your doctor may choose another dose or how often the injections should be given, based on your need.
For adults and adolescents (12 years of age and above), the recommended dose is 50 IU of Esperoct per kg body weight every 4 days. Your doctor may choose another dose or how often the injections should be given, based on your need.

To treat bleeding
The dose of Esperoct is calculated depending on your body weight and the factor VIII levels to be achieved. The target factor VIII levels will depend on the severity and location of the bleeding. Talk to your doctor if your bleeding is not being controlled with your usual dose of Esperoct.

Use in children and adolescents
For children (below 12 years of age), the recommended dose is 65 IU of Esperoct per kg body weight twice weekly. Adolescents (12 years of age and above) can use the same dose as adults.

If you use more Esperoct than you should
If you use more Esperoct than you should, contact your doctor straight away.

Always use Esperoct exactly as your doctor has told you. You should check with your doctor if you are not sure. For further information, see "Development of 'factor VIII inhibitors' (antibodies)" in section 2.

If you forget to use Esperoct
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.

If you stop using Esperoct
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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Allergic reactions (hypersensitivity)

Stop the injection immediately if you develop severe and sudden allergic reactions (anaphylactic reactions). You must contact your doctor or an emergency unit immediately if you have signs of an allergic reaction such as:
- difficulty in swallowing or breathing
- wheezing
- chest tightness
- redness and/or swelling of the lips, tongue, face or hands
- rash, hives, weals or itching
- pale and cold skin, fast heartbeat, or dizziness (low blood pressure)
- headache, feeling sick (nausea) or being sick (vomiting).

Development of 'factor VIII inhibitors' (antibodies)
If you have previously received more than 150 days of treatment with factor VIII, inhibitors (antibodies) may develop (may affect up to 1 in 100 people). If this happens, your medicine may stop working properly and you may experience persistent bleeding. If this happens, you should contact your doctor immediately. See "Development of 'factor VIII inhibitors' (antibodies)" in section 2.

The following side effects have been observed with Esperoct

Very common side effects (may affect more than up to 1 in 10 people)
- factor VIII inhibitors (antibodies) in patients not previously treated with factor VIII.

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.

Uncommon side effects (may affect up to 1 in 100 people)
- allergic reactions (hypersensitivity). These may become severe and could be life-threatening, see "Allergic reactions (hypersensitivity)" above for more information
- factor VIII inhibitors (antibodies) in patients previously treated with factor VIII.

Other possible side effects (unknown frequency)
Decreased factor VIII activity in the absence of factor VIII inhibitors.
A temporary response from your immune system might occur in the beginning of your treatment, which could make your medicine work less well.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, Website: https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Esperoct

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 pre-filled syringe labels after 'EXP'. The expiry date refers to the last day of that month.

Before reconstitution (before the powder is mixed with the solvent):

Store in a refrigerator (2 °C – 8 °C). Esperoct can be kept
- at room temperature (≤30 °C) for a single period for up to 1 year within the shelf life of the product **or**
- above room temperature (>30 °C up to 40 °C) for a single period for up to 3 months within the shelf life of the product.

When you start to store Esperoct outside the refrigerator, record the date and the storage temperature in the space provided on the carton.
Once you have taken the product out of the refrigerator for storage you must not store it again in the refrigerator.Do not freeze. Store in the original package in order to protect from light.

After reconstitution (after the powder has been mixed with the solvent – 500 IU, 1000 IU, 1500 IU, 2000 IU, 3000 IU):
Once you have reconstituted Esperoct, it should be used immediately. If you cannot use the reconstituted solution immediately, it should be used within
- 24 hours when stored in a refrigerator (2 °C – 8 °C) **or**
- 4 hours at ≤30 °C **or**
- 1 hour between >30 °C and 40 °C, only if the product was stored above room temperature (>30 °C up to 40 °C) before reconstitution for no longer than 3 months.

After reconstitution (after the powder has been mixed with the solvent - 4 000 IU, 5 000 IU):
Chemical and physical inuse stability have been demonstrated for:
• 24 hours when stored in a refrigerator (2 °C - 8 °C) or
• 4 hours at ≤ 30 °C.

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

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Esperoct contains
- The active substance is turoctocog alfa pegol (pegylated human coagulation factor VIII (rDNA)). Each vial of Esperoct contains nominally 500, 1000, 1500, 2000, 3000, 4000 or 5000 IU turoctocog alfa pegol.
- The other ingredients are L-histidine, sucrose, polysorbate 80, sodium chloride, L-methionine, calcium chloride dihydrate, sodium hydroxide and hydrochloric acid.
- The ingredients in the solvent are sodium chloride 9 mg/mL (0.9%) solution for injection and water for injections.

See section 2 “Esperoct contains sodium”.
After reconstitution with the supplied solvent (sodium chloride 9 mg/mL (0.9%) solution for injection), the prepared solution for injection contains 125, 250, 375, 500, 750, 1000 or 1250 IU turoctocog alfa pegol per mL, respectively (based on the strength of turoctocog alfa pegol, i.e. 500, 1000, 1500, 2000, 3000, 4000 or 5000 IU).

What Esperoct looks like and contents of the pack
Esperoct is available in packs containing 500 IU, 1000 IU, 1500 IU, 2000 IU, 3000 IU, 4000 IU or 5000 IU. Each pack of Esperoct contains a vial with white to off-white powder, a 4 mL pre-filled syringe with a clear colourless solvent, a plunger rod and a vial adapter.

Marketing Authorisation Holder and Manufacturer
Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd, Denmark

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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 sodium chloride 9 mg/mL (0.9%) solution for injection. The reconstituted product must be injected into your vein (intravenous (IV) 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 pre-filled 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.

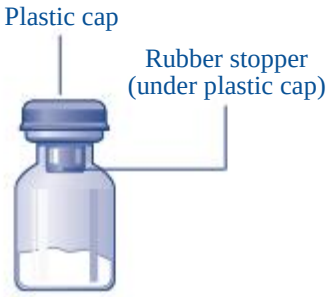
The equipment is for single use only.

Contents

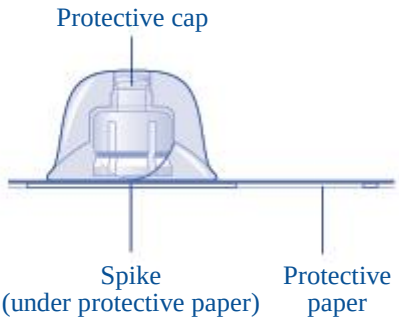
The package contains:
- 1 vial with Esperoct powder
- 1 vial adapter
- 1 pre-filled syringe with solvent
- 1 plunger rod (placed under the syringe)

Overview

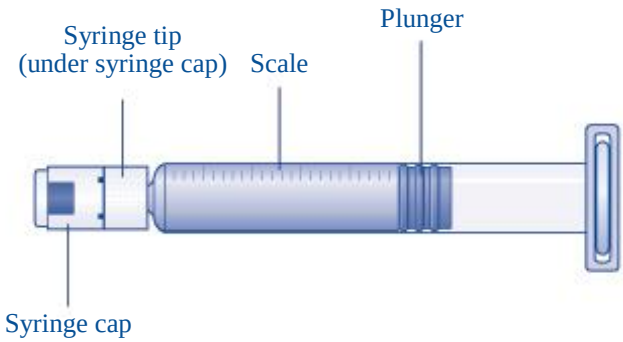
Vial with Esperoct powder



Vial adapter

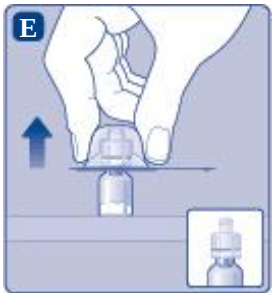
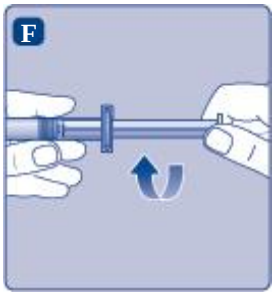


Pre-filled syringe with solvent



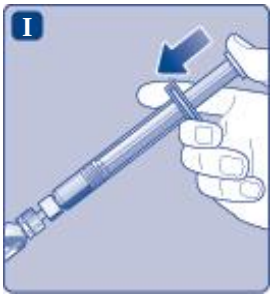
Plunger rod

1. Prepare the vial and the syringe • **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 pre-filled syringe out of the carton. **Leave the plunger rod untouched in the carton.** • **Bring the vial and the pre-filled syringe to room temperature.** You can do this by holding them in your hands until they feel as warm as your hands, see figure **A**. **Do not use any other way to warm** the vial and pre-filled syringe.	
• **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 • **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.	

• **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.**	
• 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 • 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 pre-filled syringe until resistance is felt.	
• **Remove the syringe cap** from the pre-filled 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 pre-filled syringe.**	
• **Screw the pre-filled syringe securely** onto the vial adapter until resistance is felt.	

4. Reconstitute the powder with the solvent

- **Hold the pre-filled syringe slightly tilted** with the vial pointing downwards.
- **Push the plunger rod** to inject all the solvent into the vial.



- **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 (applies to 500 IU, 1 000 IU, 1 500 IU, 2 000 IU, 3 000 IU), it should be used within:
- 24 hours when stored in a refrigerator (2 °C – 8 °C) or
- 4 hours (≤30 °C) or
- 1 hour between >30 °C and 40 °C, only if the product was stored above room temperature (>30 °C up to 40 °C) before reconstitution for no longer than 3 months.

If you cannot use the reconstituted Esperoct solution immediately (applies to 4 000 IU, 5 000 IU), it should be used within:
- 24 hours when stored in a refrigerator (2 °C – 8 °C) or
- 4 hours (≤ 30 °C).

Store the reconstituted product in the vial.

Do not freeze the reconstituted solution or store it in syringes.

Keep the reconstituted solution out of direct light.

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

- **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.

- **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 medicines.

Injecting Esperoct via needleless connectors for intravenous (IV) catheters

Caution: The pre-filled 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 pre-filled syringe. This incompatibility may prevent administration of the medicine 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 sodium chloride 9 mg/mL (0.9%) solution for injection.

Disposal

- **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 pharmacist.

  Do not throw it out with the ordinary household waste.

Do not disassemble the equipment before disposal.

Do not reuse the equipment.