

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

NovoSeven® RT 1 mg (50 KIU)

NovoSeven® RT 2 mg (100 KIU)

NovoSeven® RT 5 mg (250 KIU)

Powder and solvent for solution for injection

Active ingredient: eptacog alfa (activated)

Inactive ingredients and allergens in this medicine: See section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine.

If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

NovoSeven RT is intended to treat bleeding and to prevent excessive bleeding after surgery or other invasive treatments in the following specific groups of patients:

- if you were born with hemophilia and do not respond normally to treatment with coagulation factors VIII or IX
- if you have acquired hemophilia
- if you have Factor VII deficiency
- if you have Glanzmann's thrombasthenia (a bleeding disorder) and your condition cannot be treated effectively with platelet transfusion, or if no platelets are available.

Therapeutic group: blood coagulation factors.

NovoSeven RT is a blood coagulation factor. It works by making the blood clot at the site of bleeding when the body's own clotting factors are not working. Early treatment with NovoSeven RT reduces how much you bleed and for how long. It works in all types of bleeds, including in bleeding joints. This reduces the need for hospitalization and days absent from work and school.

2. Before using this medicine

Do not use this medicine if:

- | |
|--|
| <ul style="list-style-type: none">• you are sensitive (allergic) to eptacog alfa or any of the other ingredients in this medicine (listed in section 6 'Additional information')• you are allergic to mouse, hamster, or cow proteins (such as cows' milk). |
|--|

Special warnings about using this medicine

Before taking NovoSeven RT, tell your doctor if:

- you have recently had surgery
 - you recently had a crush injury
 - your arteries are narrowed by disease (atherosclerosis)
 - you have an increased risk of blood clots (thrombosis)
 - you have severe liver disease
 - you have a serious blood infection
 - you are prone to disseminated intravascular coagulation (DIC, a condition where blood clots develop throughout the blood stream); you must be carefully monitored.
- If any of these conditions apply to you, talk to your doctor before using the injection.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Do not use NovoSeven RT at the same time as prothrombin complex concentrates or rFXIII. Talk to your doctor before using NovoSeven RT if you also use Factor VIII or IX products.

There is limited experience of using NovoSeven RT together with medicines called antifibrinolytic drugs (such as aminocaproic acid or tranexamic acid) which are also used to control bleeding. You should talk to your doctor before using NovoSeven RT with these medicines.

Pregnancy, breastfeeding, and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you use NovoSeven RT.

Driving and using machines

There are no studies on the effect of NovoSeven RT on the ability to drive and use machines. However, there is no medical reason to think that it would affect your ability.

Important information about some of this medicine's ingredients

This medicine contains less than 1 mmol sodium (23 mg) per injection, so this medicine is essentially 'sodium free'.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine. The recommended dosage is usually:

Dose

The first dose should be given as early as possible after bleeding has started. Talk to your doctor about when to use the injections and how long to keep using them.

Your doctor will work out your dose based on your body weight, condition, and type of bleed.

To achieve the best results, follow the prescribed dose carefully. Your doctor might change the dose.

If you have hemophilia:

The usual dose is 90 micrograms for every 1 kilogram you weigh; you can repeat the injection every 2-3 hours until bleeding is controlled.

Your doctor may recommend a single dose of 270 micrograms for every 1 kilogram you weigh. There is no clinical experience in people over 65 using this single dose.

If you have Factor VII deficiency:

The usual dose range is 15 to 30 micrograms for every 1 kilogram you weigh, for each injection.

If you have Glanzmann's thrombasthenia:

The usual dose is 90 micrograms (range is 80 to 120 micrograms) for every 1 kilogram you weigh, for each injection.

Do not exceed the recommended dose.

When to treat yourself

Start treatment of a bleed as early as possible, ideally within 2 hours.

- In cases of a mild or moderate bleed, you should treat yourself as early as possible, preferably at home.
- In case of a severe bleed you should contact your doctor. Severe bleeds are usually treated in hospital and you can inject yourself with the first dose of NovoSeven RT on the way there.

Do not treat yourself for longer than 24 hours without consulting your doctor.

- Each time you use NovoSeven RT, tell your doctor or hospital as soon as possible.
- If bleeding is not controlled within 24 hours, contact your doctor immediately. You will usually

need hospital care.

Taking this medicine

- The NovoSeven powder must be dissolved in its solvent and injected into a vein. See detailed instructions further in the leaflet.

If you accidentally inject a higher dose

If you have injected an overdose, or if a child has accidentally injected or swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to inject this medicine

If you forget an injection, or if you want to stop the treatment, consult your doctor. Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine.

Wear glasses if you need them. If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using NovoSeven RT may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Serious side effects

If you notice any of the following serious side effects, seek immediate medical assistance and explain that you have used NovoSeven RT:

Rare (may affect up to 1 in 1,000 treatment episodes)

- Allergic, hypersensitivity or anaphylactic reactions. Signs may include skin rashes, itching, flushing and hives; wheezing or difficulty breathing; feeling faint or dizzy; severe swelling of the lips or throat, or at the injection site.
- Blood clots in arteries in the heart (which could lead to a heart attack or angina), in the brain (which could lead to a stroke) or in the intestine and kidneys. Signs may include severe pain in the chest, breathlessness, confusion, difficulty with speech or movement (paralysis) or abdominal pain.

Uncommon (may affect up to 1 in 100 treatment episodes)

- blood clots in veins in the lungs, legs, liver, kidneys or at the site of injection. Signs may include difficulty in breathing, red and painful swelling in the leg, and abdominal pain.
- lack of effect or decreased response to treatment.

Remind your doctor if you have a history of allergic reactions as you may need to be monitored more carefully. In most cases of blood clots, the patients were predisposed to blood clotting disorders.

Other side effects

Rare (may affect up to 1 in 1,000 treatment episodes)

- nausea
- headache
- changes in some liver and blood tests.

Uncommon (may affect up to 1 in 100 treatment episodes)

- allergic skin reactions including rash, itching and hives
- fever.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions:

Store powder and solvent below 25°C.

Store powder and solvent protected from light.

Do not freeze.

Use NovoSeven RT immediately after dissolving the powder in the solvent to avoid infection. If you cannot use it immediately after dissolving, store it in the vial with the vial adapter and syringe still attached in a refrigerator at 2°C to 8°C for no longer than 24 hours.

Do not freeze the reconstituted NovoSeven RT solution and keep it protected from light. Do not store the solution without advice from your doctor or nurse.

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. Additional information

In addition to the active ingredient, this medicine also contains:

Powder:

mannitol, sucrose, sodium chloride, calcium chloride dihydrate, glycylglycine, methionine, polysorbate 80.

Solvent:

histidine, water for injections.

The powder for solution for injection contains:

1 mg/vial (corresponding to 50 KIU/vial),

2 mg/vial (corresponding to 100 KIU/vial),

5 mg/vial (corresponding to 250 KIU/vial),

After reconstitution, 1 ml of the solution contains 1 mg eptacog alfa (activated).

1 KIU is equivalent to 1,000 IU (International Units).

What the medicine looks like and contents of the pack:

The powder vial contains white powder and the pre-filled syringe contains a clear, colorless solution.

The reconstituted solution is colorless.

Do not use the reconstituted solution if you notice particles in it or if it is discolored.

Each NovoSeven RT pack contains:

- 1 vial with white powder for reconstituting a solution for injection
- 1 vial adaptor
- 1 pre-filled syringe with solvent for reconstitution
- 1 plunger rod

Pack sizes: 1 mg (50 KIU), 2 mg (100 KIU), and 5 mg (250 KIU).

Please refer to outer packaging for present pack size.

Registration holder's name and address:

Novo Nordisk Ltd., 1 Atir Yeda Street, Kfar-Saba, 4464301.

Manufacturer's name and address:

Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvmrd, Denmark

This leaflet was revised in January 2021.

Registration number of the medicine in the Ministry of Health's National Drug Registry:

NovoSeven RT 1 mg 142-63-32929

NovoSeven RT 2 mg 142-64-32930

NovoSeven RT 5 mg 142-65-32931

Instructions for using NovoSeven RT

Read these instructions carefully before using NovoSeven RT.

NovoSeven RT is supplied as a powder. Before injection (administration) it must be dissolved in the solvent supplied in the syringe. The solvent is a histidine solution. The reconstituted NovoSeven RT must be injected into your vein (intravenous injection). The equipment in this package is designed to reconstitute and inject NovoSeven RT.

You will also need an administration set (tubing and butterfly needle, sterile alcohol swabs, gauze pads and plasters). These devices are not included in the NovoSeven RT 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 medication directly into the vein, it is important to **use a clean and germ free (aseptic) technique**. Improper technique can introduce germs that can infect the 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 is expired. Use a new package instead. The expiry date is printed after 'EXP' on the outer carton, on the vial, on the vial adaptor 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.

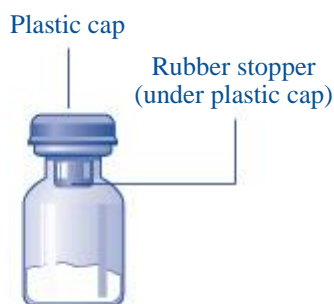
Contents

The package contains:

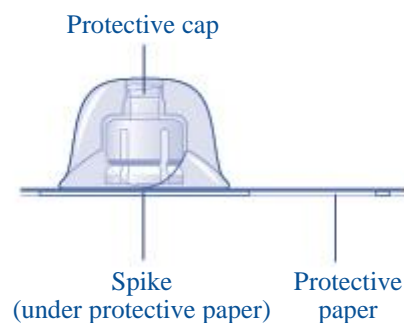
- 1 vial with NovoSeven RT powder
- 1 vial adaptor
- 1 pre-filled syringe with solvent
- 1 plunger rod (placed under the syringe)

Overview

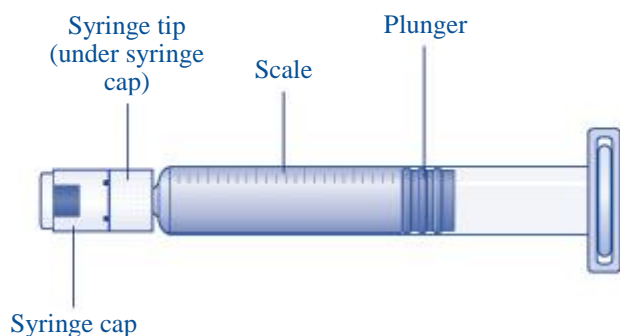
Vial with NovoSeven[®] RT powder



Vial adaptor



Pre-filled syringe with solvent

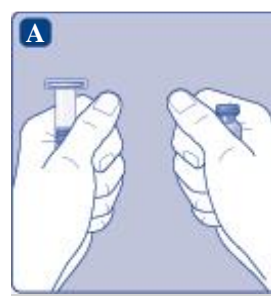





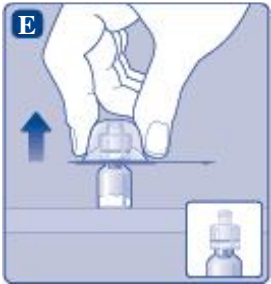
Plunger rod

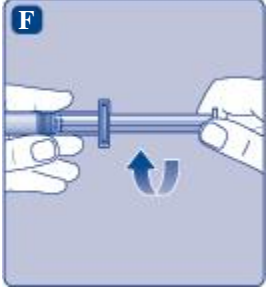





1. Prepare the vial and the syringe

- **Take out the number of NovoSeven RT packages you need.**
- **Check the expiry date.**
- **Check the name, strength and color** of the package, to make sure it contains the correct product.
- **Wash your hands** and dry them properly using a clean towel or allow them to 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** (not above 37°C). 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 pre-filled syringe.



<ul style="list-style-type: none"> • 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. 	
<p>2. Attach the vial adapter</p> <ul style="list-style-type: none"> • Remove the protective paper from the vial adapter. <p>If the protective paper is not fully sealed or if it is broken, do not use the vial adapter.</p> <p>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.</p>	
<ul style="list-style-type: none"> • Place the vial on a flat and solid surface. • Turn over the protective cap, and snap the vial adapter onto the vial. <p>Once attached, do not remove the vial adapter from the vial.</p>	
<ul style="list-style-type: none"> • Lightly squeeze the protective cap with your thumb and index finger as shown. <p>Remove the protective cap from the vial adapter.</p> <p>Do not lift the vial adapter from the vial when removing the protective cap.</p>	

<p>3. Attach the plunger rod and the syringe.</p> <ul style="list-style-type: none"> Grasp the plunger rod by the wide 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. <p>Immediately connect the plunger rod to the syringe by turning it clockwise into the plunger inside the pre-filled syringe until resistance is felt.</p>	
<ul style="list-style-type: none"> Remove the syringe cap from the pre-filled syringe by bending it down until the perforation breaks. <p>Do not touch the syringe tip under the syringe cap. If you touch the syringe tip, germs from your fingers can be transferred.</p> <p>If the syringe cap is loose or missing, do not use the pre-filled syringe.</p>	
<ul style="list-style-type: none"> Screw the pre-filled syringe securely onto the vial adapter until resistance is felt. 	
<p>4. Dissolve the powder in the solvent</p> <ul style="list-style-type: none"> Hold the pre-filled syringe slightly tilted with the vial pointing downwards. Push the plunger rod to inject all the solvent into the vial. 	
<ul style="list-style-type: none"> Keep the plunger rod pressed down and swirl the vial gently until all the powder is dissolved. <p>Do not shake the vial as this will cause foaming.</p> <ul style="list-style-type: none"> Check the reconstituted solution. It must be colorless. If you notice visible particles or discoloration, do not use it. Use a new package instead. 	



Use the dissolved NovoSeven RT immediately to avoid infections.

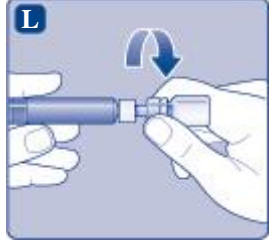

If you cannot use the medicine at once, see section 5 '*How to store this medicine*' in the first part of this leaflet. Do not store the reconstituted solution without advice from your doctor or nurse.

! 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 only need part of the reconstituted solution, use the scale on the syringe to see how much of the solution you withdraw, as instructed by your doctor or nurse.
- If, at any point, there is too much 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.

	
<p>Injecting NovoSeven RT with pre-filled syringe via needleless connectors for intravenous (IV) catheters</p> <p>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 drug and/or result in damage to the needleless connector.</p> <p>Follow the instructions for use for the needleless connector. Administration through a needleless connector may require withdrawal of the reconstituted solution into a standard 10 ml sterile luer-lock plastic syringe. This should be done right after step J.</p>	
<p>5. Inject the reconstituted solution</p> <p>NovoSeven RT is now ready to inject into your vein.</p> <ul style="list-style-type: none"> • Inject the reconstituted solution as instructed by your doctor or nurse. • Inject slowly over 2 to 5 minutes. <p>Injecting the solution via a central venous access device (CVAD) such as a central venous catheter or a subcutaneous port:</p> <ul style="list-style-type: none"> • 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. • If the CVAD line needs to be flushed before or after NovoSeven RT injection, use sodium chloride 9 mg/ml solution for injection. 	
<p>Disposal</p> <ul style="list-style-type: none"> • After injection, safely dispose of the syringe with the administration set, the vial with the vial adapter, any unused NovoSeven RT and other waste materials as instructed by your doctor or nurse. • Do not throw them out with the ordinary household waste. 	
<p>Do not disassemble the equipment before disposal. Do not reuse the equipment.</p>	