

Package leaflet: Information for the user

NovoSeven®

1 mg (50 KIU)

2 mg (100 KIU)

5 mg (250 KIU)

8 mg (400 KIU)

powder and solvent for solution for injection

eptacog alfa (activated)

Read all of this leaflet carefully before you are given this injection 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 NovoSeven® is and what it is used for**
2. **What you need to know before you use NovoSeven®**
3. **How to use NovoSeven®**
4. **Possible side effects**
5. **How to store NovoSeven®**
6. **Contents of the pack and other information**

Overleaf: Instructions on how to use NovoSeven®

1. What NovoSeven® is and what it is used for

NovoSeven® 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.

NovoSeven® is used to treat bleeding, and to prevent excessive bleeding after surgery or other important treatments. Early treatment with NovoSeven® reduces how much you bleed and for how long. It works in all types of bleeds, including joint bleeds. This reduces the need for hospitalisation and days absent from work and school.

It is used in certain groups of people:

- If you were *born with haemophilia* and do not respond normally to factors VIII or IX treatment
- If you have *acquired haemophilia*
- 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 platelets are not readily available.

NovoSeven can also be given to you by a doctor to treat heavy bleeding after delivery of your baby, even if you do not have a bleeding disorder.

2. What you need to know before you use NovoSeven®

Do not use NovoSeven®

- If you are **allergic to eptacog alfa** (active compound of NovoSeven®) or any of the other ingredients in this medicine (listed in section 6).
- If you are **allergic to mouse, hamster or cow proteins** (such as cows' milk).

- ▶ If any of these apply to you, **do not use NovoSeven®. Talk to your doctor.**

Warnings and precautions

Before treatment with NovoSeven®, make sure your doctor knows:

- If you have just had **surgery**
- If you recently had a **crush injury**
- If your **arteries are narrowed** by disease (atherosclerosis)
- If you have an increased risk of **blood clots** (thrombosis)
- If you have severe **liver disease**
- If you have a serious **blood infection**
- If 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.**

Other medicines and NovoSeven®

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

Do not use NovoSeven® at the same time as *prothrombin complex concentrates* or rFXIII. You should talk to your doctor before using NovoSeven® if you also use Factor VIII or IX products.

There is limited experience of using NovoSeven® 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® with these medicines.

Pregnancy, breast-feeding and fertility

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 you use NovoSeven®.

Driving and using machines

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

NovoSeven® contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per injection, i.e. essentially 'sodium-free'.

3. How to use NovoSeven®

The NovoSeven® powder must be reconstituted with its solvent and injected into a vein. See overleaf for detailed instructions.

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, ideally at home.
- **In case of a severe bleed** you should contact your doctor. Usually severe bleeds are treated at the hospital and you can give yourself the first NovoSeven® dose on the way there.

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

- Each time you use NovoSeven®, **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.**

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.

The dose will be worked out by your doctor, 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 haemophilia:

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.

If you inject more NovoSeven[®] than you should

If you inject too much NovoSeven[®], get medical advice at once.

If you forget an injection of NovoSeven[®]

If you forget an injection, or if you want to stop the treatment, get your doctor's advice.

4. Possible side effects

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

Serious side effects

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; and 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 the veins in lungs, legs, liver, kidneys or at 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.

► **If you notice any of these serious side effects, get medical help immediately.** Explain that you have been using NovoSeven[®].

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 rare side effects

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

- Nausea (feeling sick)

- Headache
- Changes in some liver and blood tests.

Other uncommon side effects

(may affect up to 1 in 100 treatment episodes)

- Allergic skin reactions including rash, itching and hives
- Fever.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard 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 NovoSeven®

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date that is stated on the carton. The expiry date refers to the last day of that month.
- Store powder and solvent below 25°C.
- Store powder and solvent protected from light.
- Do not freeze.
- **Use NovoSeven® at once** after mixing the powder with the solvent to avoid infection. If you cannot use it immediately, after it has been mixed, you should 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 mixed NovoSeven® 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. Contents of the pack and other information

What NovoSeven® contains

- The active substance is recombinant coagulation factor VIIa (activated eptacog alfa).
- The other ingredients in the powder are sodium chloride, calcium chloride dihydrate, glycylglycine, polysorbate 80, mannitol, sucrose, methionine, hydrochloric acid, sodium hydroxide. The ingredients in the solvent are histidine, hydrochloric acid, sodium hydroxide, 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) or 8 mg/vial (corresponding to 400 KIU/vial).

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

1 KIU equals 1,000 IU (International Units).

What NovoSeven® looks like and contents of the pack

The powder vial contains white powder and the pre-filled syringe contains a clear colourless solution. The reconstituted solution is colourless. Do not use the reconstituted solution if you notice particles in it or if it is discoloured.

Each NovoSeven® pack contains:

- 1 vial with white powder for solution for injection

- 1 vial adapter
- 1 pre-filled syringe with solvent for reconstitution
- 1 plunger rod

Pack sizes: 1 mg (50 KIU), 2 mg (100 KIU), 5 mg (250 KIU) and 8 mg (400 KIU).
Please refer to outer packaging for present pack size.

Marketing Authorisation Holder and Manufacturer

Novo Nordisk A/S
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DK-2880 Bagsværd, Denmark

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Instructions on how to use NovoSeven®

READ THESE INSTRUCTIONS CAREFULLY BEFORE USING NOVOSEVEN®

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

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® 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 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.

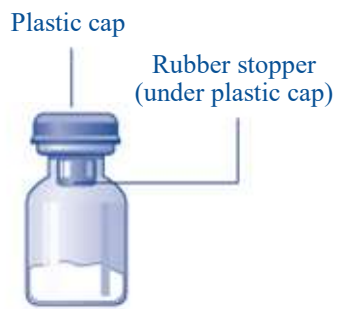
Contents

The package contains:

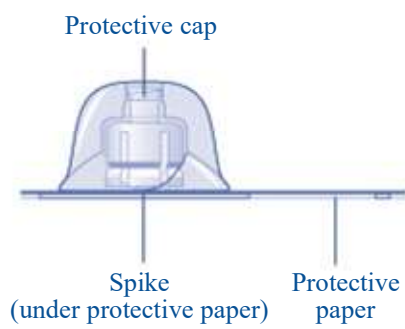
- 1 vial with NovoSeven® powder
- 1 vial adapter
- 1 pre-filled syringe with solvent
- 1 plunger rod (placed under the syringe)

Overview

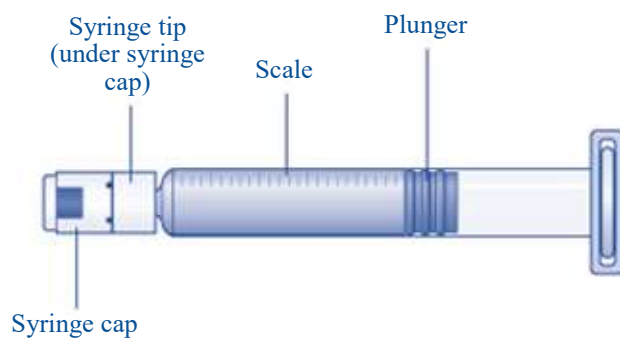
Vial with NovoSeven powder



Vial adapter






Pre-filled syringe with solvent


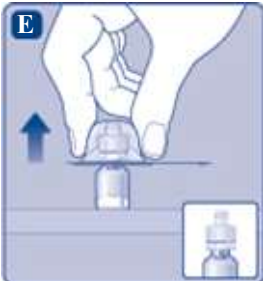
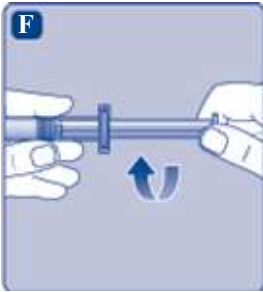




Plunger rod



1. Prepare the vial and the syringe

<ul style="list-style-type: none"> • Take out the number of NovoSeven® 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 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 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. <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. Reconstitute the powder with 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.



- **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 colourless. **If you notice visible particles or discolouration, do not use it.** Use a new package instead.



Use the reconstituted NovoSeven[®] at once to avoid infections.

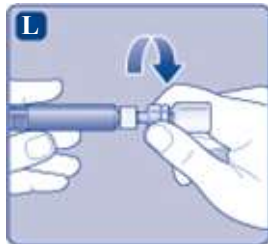

If you cannot use it at once, see section 5 *How to store NovoSeven[®]* on the other side of this leaflet. Do not store the reconstituted solution without advice from your doctor or nurse.

(I)

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.
- In case 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.



<ul style="list-style-type: none"> • 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® 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® 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® 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® and other waste materials as instructed by your doctor or nurse. • Do not throw it out with the ordinary household waste. 	
<p>Do not disassemble the equipment before disposal.</p> <p>Do not reuse the equipment.</p>	