

PACKAGE LEAFLET: INFORMATION FOR THE USER

NovoSeven 1 mg (50 KIU) powder and solvent for solution for injection
NovoSeven 2 mg (100 KIU) powder and solvent for solution for injection
NovoSeven 5 mg (250 KIU) powder and solvent for solution for injection
NovoSeven 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.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What NovoSeven is and what it is used for
2. Before you use NovoSeven
3. How to use NovoSeven
4. Possible side effects
5. How to store NovoSeven
6. Further information

Overleaf: NovoSeven user instructions

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 events and to prevent excessive bleeding connected with surgery or other invasive procedures:

- If you are born with haemophilia and do not respond normally to factors VIII or IX (due to inhibitors to coagulation factors VIII or IX or patients who are at risk of responding to factor VIII or factor IX injection with a rapid and substantial increase in inhibitors against these products).
- If you have acquired haemophilia.
- If you have Factor VII deficiency.
- If you have Glanzmann's thrombasthenia (a bleeding disorder) which can not be treated effectively with platelet transfusion.

2. BEFORE YOU USE NOVOSEVEN

Do not use NovoSeven...

- If you are allergic to any ingredient in NovoSeven, or
- If you are allergic to mouse, hamster or cow proteins

Take special care with NovoSeven and 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
- If you have severe liver disease

- If you have a serious blood infection

Patients predisposed to disseminate intravascular coagulation (DIC, a condition where blood clots develop throughout the blood stream) should be carefully monitored.

If bleeding is not kept under control, contact your doctor immediately.

If any of these apply to you, talk to your doctor before using the injection.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Simultaneous use of NovoSeven and coagulation factor concentrates should be avoided.

Experience with simultaneous use of NovoSeven and medicines used to reduce the dissolving of blood clots is limited. If you are taking such medicines you should talk to your doctor before taking NovoSeven.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, ask your doctor for advice before you use NovoSeven.

Important information about some of the ingredients of NovoSeven

If you have been told by your doctor that you have an intolerance to fructose, contact your doctor before taking NovoSeven.

3. HOW TO USE NOVOSEVEN

NovoSeven needs to be injected into a vein. In case of severe bleeds NovoSeven will be administered by a doctor or nurse in the surgery or hospital. In case of mild or moderate bleeding episodes, it may be given to you to use at home if required.

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

- Each time you use NovoSeven, tell your doctor or hospital at the earliest possible opportunity so that your progress can be monitored.
- If bleeding is not controlled, you will need hospital care.

Dosage

The dose will be worked out by your doctor, based on your body weight and your condition.

If you have haemophilia:

The usual dose is 90 µg for every 1 kg you weigh, at each injection. As an alternative your doctor may recommend a single dose of 270 µg for every 1 kg you weigh, however, there is no clinical experience in elderly using this dose.

The home therapy should not exceed 24 hours.

If you have Factor VII deficiency:

The usual dose range is 15 to 30 µg for every 1 kg you weigh, at each injection.

If you have Glanzmann's thrombasthenia:

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

For all use of NovoSeven

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

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.

Making up the injection and injecting the solution

See overleaf for detailed instructions.

4. POSSIBLE SIDE EFFECTS

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

Serious side effects

Hypersensitivity reactions are rarely reported (between 1 in 10,000 and 1 in 1,000 doses).

Furthermore, there have also been reports on the following serious side effects:

- Blood clots in arteries leading to heart attack or stroke
- Blood clots in the veins in lungs, legs or at site of injection
- Blood clots in liver predominantly in patients with liver disease or undergoing liver surgery
- Anaphylactic reactions

In the vast majority of cases reported on blood clots, the patients were predisposed to thrombotic disorders due to pre-existing risk factors.

Remind your doctor if you have a history of allergic reactions as you may need to be monitored more carefully.

Less serious side effects

Side effects as allergic skin reactions; fever and instances with inadequate response to treatment have been uncommonly observed (between 1 in 1,000 and 1 in 100 doses).

Blood tests showing changes in the way the liver functions, and nausea have been rarely reported (between 1 in 10,000 and 1 in 1,000 doses).

Tell your doctor if you notice any undesirable side effects, whether or not they are mentioned in this leaflet.

5. HOW TO STORE NOVOSEVEN

- Keep out of the reach and sight of children.
- Do not use the product after the expiry date which is stated on the outer carton and labels. 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, to prevent damage to the solvent vial.
- Although NovoSeven will be stable for 24 hours after it has been mixed, you should use it at once to avoid infection. If you do not use it immediately after mixing, you should store the vial with the syringe still attached in a refrigerator at 2°C to 8°C for no longer than 24 hours. Do not store the solution without your doctor's advice.

6. FURTHER 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 1000 IU (International Units).

What NovoSeven looks like and contents of the pack

The powder vial contains white powder and the solvent vial contains a clear colourless solution. The reconstituted solution for injection is colourless. Do not use the reconstituted solution if particle formation or discolouration is noticed.

Each NovoSeven pack contains:

- 1 vial with white powder for solution for injection
- 1 vial with solvent for reconstitution

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

Novo Allé

DK-2880 Bagsværd, Denmark

This leaflet was last approved in 10/2010

NOVOSEVEN USER INSTRUCTIONS

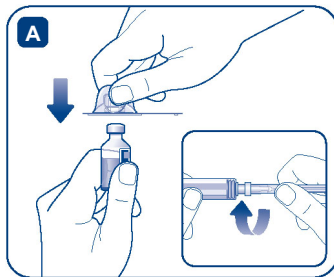


Preparing the solution

Wash your hands. NovoSeven powder and solvent vials should be at room temperature at reconstitution. Remove the plastic caps from the two vials. If the caps are loose or missing, do not use the vials. Clean the rubber stoppers on the vials with alcohol swabs and allow them to dry before use. Use a disposable syringe of an appropriate size and a vial adapter, transfer needle (20 - 26G) or other suitable device.

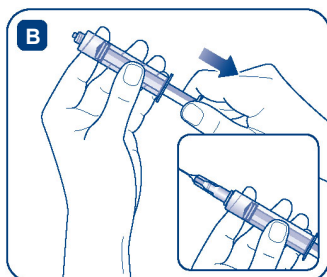
A

Remove the protective paper from the vial adapter without taking it out of the protective cap. Attach the vial adapter to the solvent vial. Once attached, remove the protective cap. Take care not to touch the spike on the vial adapter. If using a transfer needle, remove transfer needle from the packaging without taking it out of the protective cap. Screw the transfer needle tightly onto the syringe.



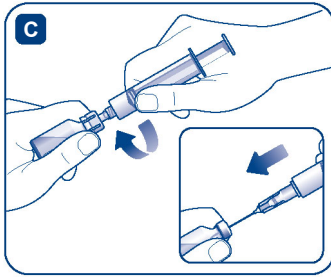
B

Pull the plunger to draw in a volume of air that is equal to the amount of solvent in the solvent vial (ml equals cc on the syringe).



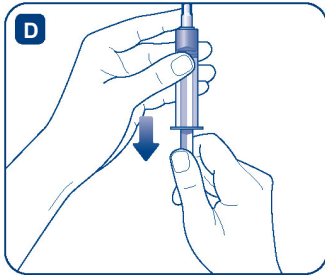
C

Screw the syringe tightly onto the vial adapter on the solvent vial. If using a transfer needle, remove the protective cap and insert the transfer needle into the rubber stopper of the solvent vial. Take care not to touch the end of the transfer needle. Inject air into the vial by pushing the plunger until you feel a clear resistance.



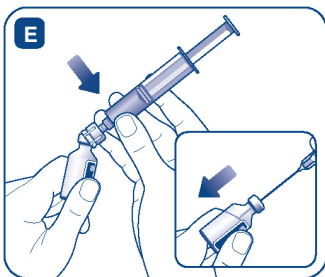
D

Hold the syringe with the solvent vial upside down. If you are using a transfer needle, make sure that the transfer needle tip is in the solvent. Pull the plunger to draw the solvent into the syringe.



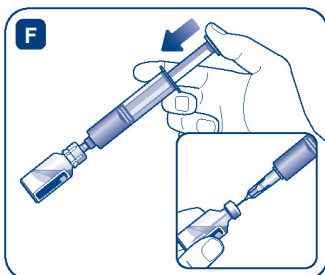
E

Remove the empty solvent vial. If you use a vial adapter, tip the syringe to remove it from the vial.



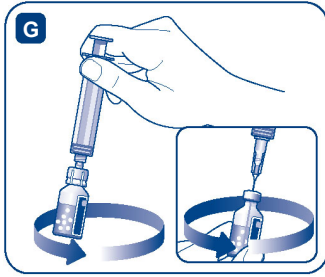
F

Attach the syringe with vial adapter or transfer needle to the powder vial. If you use a transfer needle, make sure to penetrate the centre of the rubber stopper. Hold the syringe slightly tilted with the vial facing downwards. Push the plunger slowly to inject the solvent into the powder vial. Make sure not to aim the stream of solvent directly at the NovoSeven powder as this will cause foaming.



G

Gently swirl the vial until all the powder is dissolved. Do not shake the vial as this will cause foaming. Check the solution for visible particles and discolouration. If you notice either, do not use it. NovoSeven reconstituted product is a clear, colourless solution. Keep the vial adapter or transfer needle attached to the vial.

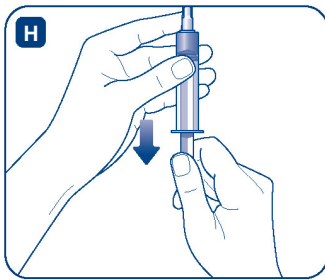


Although NovoSeven will be stable for 24 hours after it has been mixed, you should use it at once to avoid infection. If you do not use it immediately after mixing, you should store the vial with the syringe still attached in a refrigerator at 2°C to 8°C for no longer than 24 hours. Do not store the solution without your doctor's advice.

Injecting the solution

H

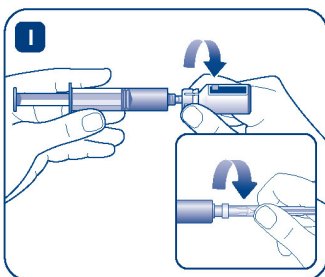
Ensure that the plunger is pushed all the way in before turning the syringe upside down (it may have been pushed out by the pressure in the syringe). If you use a transfer needle, make sure that the transfer needle tip is in the solution. Hold the syringe with the vial upside down and pull the plunger to draw all the solution into the syringe.



I

If you use a vial adapter, unscrew the vial adapter with the empty vial. If you use a transfer needle, remove the transfer needle from the vial, replace the transfer needle cap, and twist the transfer needle off the syringe.

NovoSeven is now ready for injection. Follow the injection procedure as instructed by your health care professional.



J

Safely dispose of the syringe, vials, any unused product and other waste materials as instructed by your health care professional.

