

B. PACKAGE LEAFLET

PACKAGE LEAFLET : INFORMATION FOR THE USER

NovoSeven

1.2 mg (60 KIU)

2.4 mg (120 KIU)

4.8 mg (240 KIU)

Powder and solvent for solution for injection.

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

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 episodes and to prevent excessive bleeding connected with surgery or other invasive procedures, in certain groups of people:

- **in people born with haemophilia** who do not respond normally to factors VIII or IX (due to inhibitors to coagulation factors VIII or IX or who are expected to have a high anamnestic response to factor VIII or factor IX administration)
- **in people with acquired haemophilia**
- **in people with Factor VII deficiency**
- **in people with Glanzmann's thrombasthenia.**

2. BEFORE YOU USE NOVOSEVEN

Some people should not have these injections

Do not use NovoSeven ...

- **if you are allergic to any ingredient** in NovoSeven
- **if you are allergic to mouse, hamster or cow proteins.**

If any of these applies to you, tell your doctor without taking NovoSeven.

Some people will be treated with special care

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 a serious blood infection.**

Patients predisposed to disseminated intravascular coagulation (DIC) should be carefully monitored. If any of these apply to you, talk to your doctor before using the injection.

Using other medicines

Before you use NovoSeven, talk to your doctor about any other medicine you use.

Pregnancy and breast-feeding

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

The usual dose

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

People with haemophilia

The usual dose is 90 µg for every 1 kg you weigh, at each injection.

People with Factor VII deficiency

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

People with 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 miss an injection, or if you want to stop the treatment, get your doctor's advice.

If you inject more NovoSeven than recommended

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

If you miss an injection of NovoSeven

If you forget to inject NovoSeven, get medical advice at once.

Making up the injection and injecting the solution

See overleaf for detailed instructions.

4. POSSIBLE SIDE EFFECTS

NovoSeven may cause side effects, but these are generally rare. For every 1,000 NovoSeven doses less than one side effect has been reported.

Serious side effects (very rare, less than one per 10,000 doses)

- **Blood clots in arteries** leading to heart attacks or strokes
- **Blood clots in veins** leading to pulmonary embolism.

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

Less serious side effects (very rare, less than one per 10,000 doses)

- **Rash**
- **Fever**
- **Nausea**
- **Increase in liver enzymes.**

There have been no anaphylactic reactions reported to NovoSeven, but people with a history of allergic reactions should be carefully monitored.

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

5. HOW TO STORE NOVOSEVEN

- Keep out of the reach and sight of children
- Store NovoSeven in a refrigerator (2°C - 8°C)
- Store in original package in order to protect from light
- Do not freeze, to prevent damage to the solvent vial
- Do not use the product after the expiry date. This is stated on the outer carton and labels.

6. FURTHER INFORMATION

What NovoSeven contains

- The active substance is recombinant coagulation factor VIIa (activated eptacog alfa).
- The other ingredients are sodium chloride, calcium chloride dihydrate, glycylglycine, polysorbate 80, mannitol, water for injections.

The powder for solution for injection contains: 1.2 mg/vial (corresponding to 60 KIU/vial), 2.4 mg/vial (corresponding to 120 KIU/vial) or 4.8 mg/vial (corresponding to 240 KIU/vial). After reconstitution 1 ml of the solution contains 0.6 mg eptacog alfa (activated). 1 KIU equals 1000 IU (International Units).

What NovoSeven looks like and contents of the pack

The reconstituted solution for injection is colourless.

Each NovoSeven pack contains:

- 1 vial with white powder (NovoSeven) for solution for injection
- 1 vial with solvent (Water for injections) for reconstitution
- 1 sterile vial adapter for reconstitution
- 1 sterile disposable syringe for reconstitution and administration
- 1 sterile infusion set
- 2 alcohol swabs.

Pack sizes: 1.2 mg (60 KIU), 2.4 mg (120 KIU) and 4.8 mg (240 KIU). Please refer to outer packaging for present pack size.

Marketing authorisation holder and manufacturer

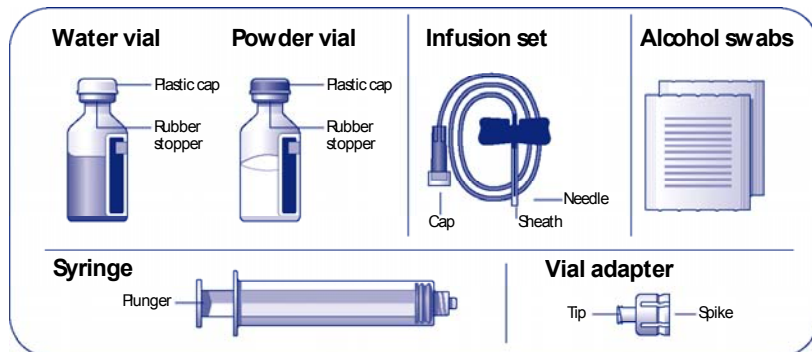
Novo Nordisk A/S

Novo Allé

DK-2880 Bagsværd, Denmark

This leaflet was last approved in

NOVOSEVEN USER INSTRUCTIONS

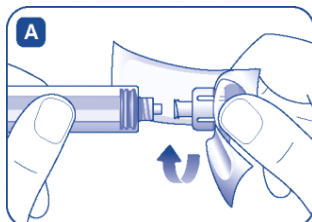


Preparing the solution

Wash your hands. Bring the NovoSeven powder and water vials to room temperature (but not above 37°C). You can do this by holding them in your hands. 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 the alcohol swabs and allow them to dry before use.

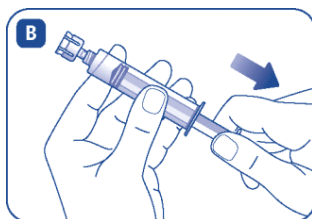
A

Take the syringe out of its package. Open the vial adapter pack. Keep the vial adapter in the pack while screwing it tightly onto the syringe. Take care not to touch the tip of the vial adapter.



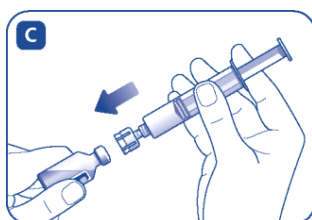
B

Pull the plunger to draw in a volume of air that is equal to the amount of water in the water vial (ml equals cc on the syringe). Take care not to touch the spike of the vial adapter.



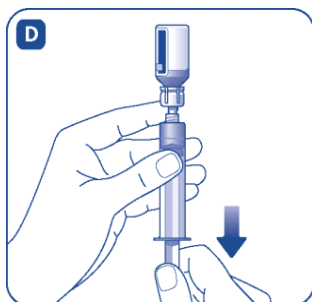
C

Click the vial adapter onto the water vial. To inject the air into the vial, push the plunger until you feel a clear resistance.



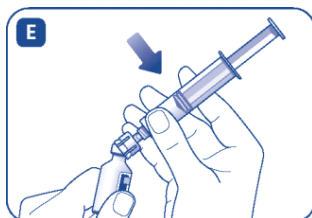
D

Hold the syringe with the water vial upside down and pull the plunger to draw the water into the syringe.



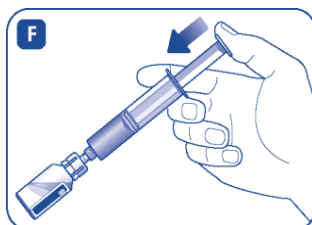
E

Remove the empty water vial by tipping the syringe with the vial adapter.



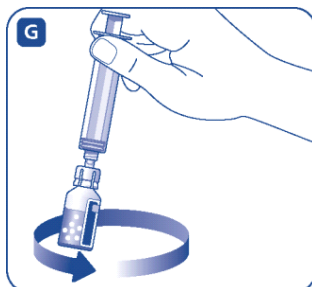
F

Click the vial adapter, still attached to the syringe, onto the powder vial. Hold the syringe slightly tilted with the vial facing downwards. Push the plunger slowly to inject the water into the powder vial. Make sure not to aim the stream of water 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 bits and discolouration. If you notice either, do not use it.



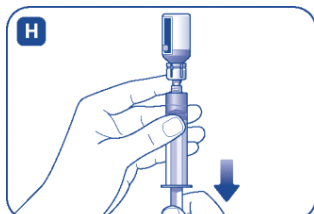
Although NovoSeven will be stable for 24 hours after it has been mixed, you should use it at once to avoid infection. If you do not use it immediately after mixing, you should store the vial with the

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

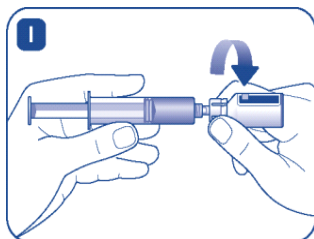
Ensure that the plunger is pushed all the way in before turning the syringe upside down (it may have been pushed out by the pressure in the syringe). Hold the syringe with the vial upside down and pull the plunger to draw all the solution into the syringe.



I

Unscrew the vial adapter with the empty vial.

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



J

Safely dispose of the syringe, vial adapter, vials, infusion set and any unused product as instructed by your health care professional.

