PATIENT INFORMATION LEAFLET

Scheduling status S4

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

eptacog alfa (activated)

Contains sugar: sucrose

Read all of this leaflet carefully before you start using NovoSeven®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- NovoSeven® has been prescribed for you personally and you should not share it with other people. It may harm them, even if their symptoms are the same as yours.

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.

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 or 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 hypersensitive (allergic) to eptagoc alfa (the active ingredient), or any of the other ingredients in NovoSeven® (listed in section 6)
- if you are allergic to mouse, hamster or cow proteins (such as cow's milk).

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

Warnings and precautions

Take special care with NovoSeven®:

- if you have just had surgery
- if you recently had a crush injury
- if your arteries are narrowed by disease (atherosclerosis)
- if you have a serious blood infection.
- if you have an increased risk of blood clots (thrombosis)
- if you have severe liver disease
- 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 apply to you, talk to your doctor before using the injection.

Other medicines and NovoSeven®:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Simultaneous use of NovoSeven® and prothrombin complex concentrates or rFXIII should be avoided.

You should talk to your doctor before using NovoSeven® if you also use factor VIII or IX products.

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

There is limited experience of using NovoSeven® together with medicines called antifibrinolytic medicines (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 and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using NovoSeven®.

Driving and using machines:

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

NovoSeven® contains sucrose:

NovoSeven® contains the sugar called sucrose which consists of fructose and glucose. If you have been told by your doctor that you have an intolerance to sucrose, fructose or glucose or that you cannot absorb properly contact your doctor before using NovoSeven®.

NovoSeven® contains sodium:

NovoSeven® contains less than 1 mmol sodium (23 mg) per injection, indicating that it is essentially "sodium free".

3. How to use NovoSeven®

Do not share medicines prescribed for you with any other person.

Always use NovoSeven® exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

NovoSeven® powder must be reconstituted with its solvent and needs to be injected into a vein.

When to treat yourself

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

- 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 within 24 hours, contact your doctor immediately, you will 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 usual dose will be worked out by your doctor, based on your body weight and your 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 µg for every 1 kg you weigh, at each injection, you can repeat the injection every 2 – 3 hours until bleeding is controlled.

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, for 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, for each injection.

If you have acquired haemophilia

The recommended initial dose, administered by intravenous bolus injection, is 90 µg per kg body weight. Following the initial dose of NovoSeven® further injections may be given if required.

For all use of NovoSeven®

- Consult 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.

Making up the injection and injecting the solution

See overleaf for detailed instructions.

If you inject more NovoSeven® than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Always take the labelled medicine package with you, whether there are any NovoSeven® left or not.

If you missed a dose of NovoSeven®

If you forget to inject NovoSeven®, or if you want to stop treatment, get medical advice at once.

Do not take a double dose to make up for the forgotten individual dose.

4. Possible side effects

NovoSeven® can have side effects.

Not all side effects reported for NovoSeven® medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using NovoSeven®, please consult your health care provider for advice.

If any of the following happens, stop using NovoSeven® and tell your doctor immediately or go to the casualty department at

your nearest hospital:

Less frequently occurring:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in

swallowing or breathing, wheezing.

- Rash or itching, flushing and hives.
- Fainting, or dizziness.

These are all very serious side effects. If you have them, you may have had a serious reaction to NovoSeven®. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the following:

Less frequently occurring:

- **Blood clots in arteries** leading to heart attacks or strokes. Signs may include severe pain in the chest, breathlessness, confusion, difficulty with speech or movement (paralysis) or abdominal pain.
- **Blood clots in veins in the lungs** (leading to pulmonary embolism), legs, kidneys. 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®.

Tell your doctor if you notice any of the following:

Less frequently occurring:

- Nausea
- Headache
- Changes in some liver and blood tests
- Fever

People with a history of allergic reactions should be carefully monitored.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of NovoSeven®.

5. How to store NovoSeven®

- Store all medicines out of reach of children.
- Store NovoSeven® powder and solvent at or below 25 °C.
- Store NovoSeven® in original package in order to protect from light.
- Avoid freezing NovoSeven® to prevent damage to the solvent pre-filled syringe.
- Do not freeze the reconstituted solution.
- After reconstitution of NovoSeven®, chemical and physical stability has been demonstrated for 6 hours at 25 °C and 24 hours at 2 °C – 8 °C.
- Use NovoSeven® at once after mixing the powder with the solvent to avoid infection. If you cannot use it immediately, after it has been reconstituted, you should store it in the vial with the vial adapter and syringe still attached in a refrigerator at 2 °C – 8 °C for no longer than 24 hours.
- Do not use the NovoSeven® after the expiry date stated on the outer carton and labels.
- Discard any unused product as instructed by your health care provider.

How to dispose of NovoSeven®

Safely dispose of all unused and or expired NovoSeven® as instructed by your health care provider or return it to your nearest pharmacy. Medicines should not be disposed of via drains, sewerage systems or household waste.

6. Contents of the pack and other information

What NOVOSEVEN® contains

- The active substance is recombinant coagulation factor VIIa, eptacog alfa (activated).
- The other ingredients in the powder are: sodium chloride, calcium chloride dihydrate, glycylglycine, polysorbate 80, mannitol, sucrose, methionine, hydrochloric acid, sodium hydroxide.

  The other ingredients in the solvent are: histidine, hydrochloric acid, sodium hydroxide, water for injections.

What NOVOSEVEN® looks like and contents of the pack:

Freeze-dried powder: A white, homogenous lyophilisate.

Histidine solvent: A clear, colourless solution.

Reconstituted product: A clear, colourless solution.

NovoSeven® packages:

a) NovoSeven® 1 mg (vial/syringe presentation):

- 1 x 2 ml clear colourless, type I glass vial containing 1 mg (50 KIU) freeze-dried recombinant coagulation factor VIIa. The vial is closed with grey chlorobutyl rubber stopper, which is sealed with gold coloured aluminium cap covered with yellow red tamper-evident snap-off polypropylene cap.
- 1 x 3 ml clear colourless, type I glass prefilled syringe containing 1 ml Histidine solvent for reconstitution. The syringe consists of a glass barrel with a polypropylene backstop and bromobutyl rubber plunger. The syringe cap consists of bromobutyl rubber and polypropylene tamper evident seal. The plunger rod is made of polypropylene.

b) NovoSeven® 2 mg (vial/syringe presentation):

- 1 x 2 ml clear colourless, type I glass vial containing 2 mg (100 KIU) freeze-dried recombinant coagulation factor VIIa. The vial is closed with grey chlorobutyl rubber stopper which is sealed with a gold coloured aluminium cap covered with light blue tamper-evident snap-off polypropylene cap.

- 1 x 3 ml clear colourless, type I glass prefilled syringe containing 2 ml Histidine solvent for reconstitution. The syringe consists of a glass barrel with a polypropylene backstop and bromobutyl rubber plunger. The syringe cap consists of bromobutyl rubber and polypropylene tamper evident seal. The plunger rod is made of polypropylene.

c) NovoSeven® 5 mg (vial/syringe presentation):

- 1 x 13 ml clear colourless, type I glass vial containing 5 mg (250 KIU) freeze-dried recombinant coagulation factor VIIa. The vial is closed with grey chlorobutyl rubber stopper, which is sealed with a gold coloured aluminium cap covered with dark blue tamper-evident snap-off polypropylene cap.
- 1 x 10 ml clear colourless, type I glass prefilled syringe containing 5 ml Histidine solvent for reconstitution. The syringe consists of a glass barrel with a polypropylene backstop and bromobutyl rubber plunger. The syringe cap consists of bromobutyl rubber and polypropylene tamper evident seal. The plunger rod is made of polypropylene.

The NovoSeven® powder in vial/Histidine solvent in syringe product presentations come with a vial adaptor.

Holder of Certificate of Registration:

Novo Nordisk (Pty) Ltd

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10 Marion Street Office Park

Building C1

Sandton, Johannesburg

2196

011 202 0500

This leaflet was last revised in

24 July 2023

Registration numbers

a) NovoSeven® 1 mg: 44/8.1/0550

b) NovoSeven® 2 mg: 44/8.1/0551

c) NovoSeven® 5 mg: 44/8.1/0552

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.

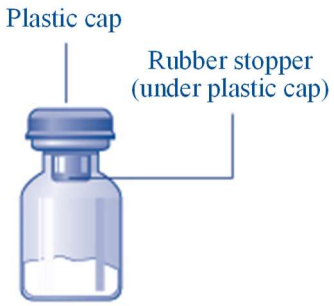
Contents

The package contains:

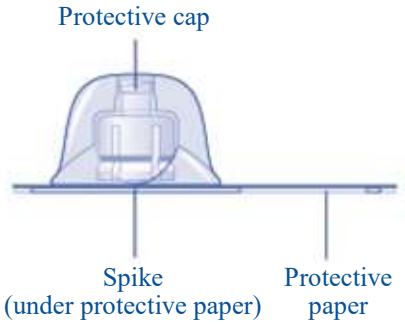
- 1 vial with NovoSeven® powder
- 1 vial adapter
- 1 pre-filled syringe with solvent
- 1 plunger rod (placed under the syringe)

Overview

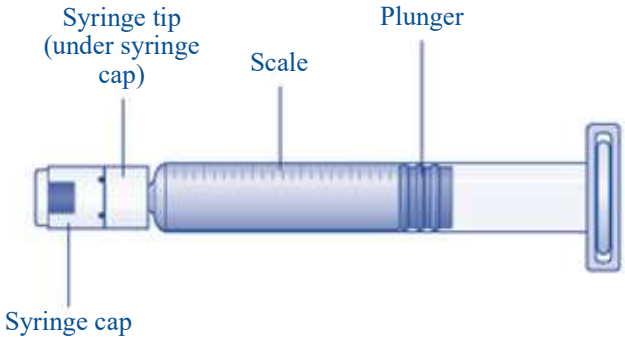
Vial with NovoSeven powder



Vial adapter



Pre-filled syringe with solvent

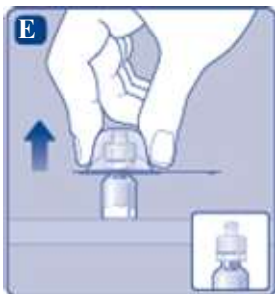
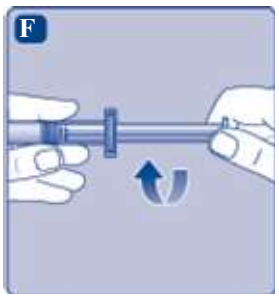


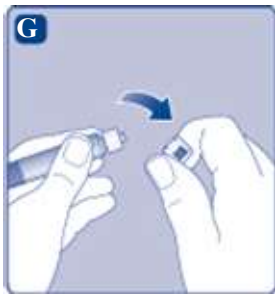
Plunger rod



1. Prepare the vial and the syringe • **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.	
• **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 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 6.3 in the Professional Information. Do not store t 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 adapt 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.	
• **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.	

Injecting NovoSeven® with pre-filled syringe 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 drug and/or result in damage to the needleless connector.

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.

5. Inject the reconstituted solution

- NovoSeven® is now ready to inject into your vein.
- Inject the reconstituted solution as instructed by your doctor or nurse.
- Inject slowly over 2 to 5 minutes.

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.
- If the CVAD line needs to be flushed before or after NovoSeven® injection, use sodium chloride 9 mg/ml solution for injection.

Disposal

- **After injection, safely dispose** of the syringe with the infusion 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.



Do not disassemble the equipment before disposal.

Do not reuse the equipment.