

NovoSeven[®] RT

1.0mg, 2.0mg, 5.0mg and 8.0mg

eptacog alfa (activated) (bhk)

Recombinant coagulation factor VIIa

Consumer Medicine Information

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This leaflet answers some common questions about NovoSeven[®] RT. It does not contain all the available information. It does not take the place of talking to your doctor or healthcare professional.

All medicines have risks and benefits. Your doctor has weighed the risks of you using NovoSeven[®] RT against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or healthcare professional.

Keep this leaflet with the medicine. You may need to read it again.

What NovoSeven[®] RT is used for

NovoSeven[®] RT is a medicine that works by activating the blood clotting system at the site of bleeding. It is similar to the activated factor VII (7) in human blood. NovoSeven[®] RT is made by genetic engineering.

NovoSeven[®] RT is used to control bleeding episodes and to prevent excessive bleeding connected with surgery in people who have:

- inhibitors to clotting factors VIII (8) or IX (9), or
- congenital FVII deficiency,
- Glanzmann's Thrombasthenia which cannot be treated effectively with platelet transfusions.

Your doctor may want to give you NovoSeven[®] RT for another reason.

Ask your doctor or healthcare professional if you have any questions about why NovoSeven[®] RT has been given to you.

Before you use NovoSeven[®] RT

When NovoSeven[®] RT should not be used

You should not use or be treated with NovoSeven[®] RT if you have an allergy to:

- mice, hamster or cow proteins (such as cows' milk);
- NovoSeven[®] RT or any of the ingredients listed at the end of this leaflet.

If you are uncertain as to whether you have such an allergy, raise this concern with your doctor.

Do not use it after the expiry date ('Expiry') printed on the carton and label.

Do not use NovoSeven[®] RT if the packaging is torn, shows signs of tampering or does not look quite right.

Before you start to use it

Tell your doctor if you:

- are allergic to mice, hamsters or cows;

- have had a reaction to any of the ingredients in NovoSeven[®] RT;
- are using other blood clotting factors;
- have had recent surgery or a crush injury;
- are pregnant or trying to become pregnant;
- are breast-feeding or planning to breast-feed.

Tell your doctor if you have or have had any medical conditions, especially the following:

- sepsis (generalised infection);
- blood clots (thrombosis) or advanced hardening of the arteries with cholesterol deposits;
- coronary artery disease or previous heart attacks;
- stroke;
- liver disease;
- intolerance to fructose, a form of sugar.

Tell your doctor if you plan to have surgery.

If you have not told your doctor about any of the above, tell them before you use NovoSeven[®] RT.

Taking other medicines

Do not use NovoSeven[®] RT and blood clotting factor concentrates at the same time. Do not use NovoSeven[®] RT at the same time as prothrombin complex concentrates or rFXIII.

Tell your doctor before you use NovoSeven[®] RT and medicines used to reduce the dissolving of blood clots.

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Immediately before you use it

Make sure that:

- the packaging is not damaged or torn;
- the protective tamper-proof plastic caps are in place, and are not loose or missing;
- the NovoSeven[®] RT powder in the vial is white and the solvent is a clear colourless solution;
- the vial and pre-filled syringe are not damaged.

Using NovoSeven[®] RT

How to use NovoSeven[®] RT

NovoSeven[®] RT is for intravenous injection. Solvent must be added (reconstitution) to the vial of NovoSeven[®] RT powder before the solution is injected. The solution should be clear and colourless.

Patients with haemophilia:

In case of mild or moderate bleeding episodes, it may be given to you to use at home, if required. In case of severe bleeds, NovoSeven[®] RT will be administered by a doctor or nurse in the surgical or hospital.

Reconstitution and injection:

Please refer to the instructions for use.

NovoSeven[®] RT is for single use in one person only. The reconstituted NovoSeven[®] RT should be used immediately. Discard your vial after use.

When and how much to use

You will be given NovoSeven[®] RT in a dose and schedule decided by your doctor.

Do not adjust this dose or schedule without first consulting your doctor.

The dosage you are given will depend on your body weight and the reason for NovoSeven[®] RT treatment.

After you use it

- Do not refill NovoSeven[®] RT vials.
- Healthcare professionals, relatives and other carers should follow general precautionary measures for removal and disposal of needles to eliminate the risk of needlestick injury.

How long to use it

Do not stop using NovoSeven[®] RT without consulting your doctor.

If you use too much (overdose)

If you are given or if you give yourself too much NovoSeven[®] RT you should contact your doctor immediately. Your doctor will take appropriate action.

If you have any concerns about taking this medicine, ask your doctor or haemophilia nurse.

If you forget to use it

You should contact your doctor who will take the appropriate action.

While you are using NovoSeven[®] RT

Things you must do

You and your doctor should monitor your bleeding. **Tell your doctor or nurse if your bleeding gets worse.**

Things you must not do

Do not give NovoSeven[®] RT to anyone else, even if they have the same condition as you.

Do not use NovoSeven[®] RT to treat any other complaints.

Do not stop using NovoSeven[®] RT, or adjust the dosage, without checking with your doctor.

You should not continue home-treatment for longer than 24 hours. If bleeding is not controlled within 24 hours, contact your doctor immediately. You will usually need hospital care.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

On rare occasions, NovoSeven[®] RT may cause injection site reaction, rash, itching, nausea, headache, general discomfort, perspiration, changes in blood pressure, tightness of the chest, wheezing, shock,

irregular heartbeat, vomiting, fluid retention, bleeding and clotting problems, tremors, changes in kidney and liver function. Some of these symptoms may indicate you are allergic to NovoSeven[®] RT. **Contact your doctor immediately, or go to the accident and emergency department at your nearest hospital.**

Blood clots in arteries leading to heart attack or stroke have occurred on rare occasions. Blood clots at the site of injection, or in the blood vessels of the liver, kidney, lungs, gut or limbs have occurred but are uncommon. Blood clots in the heart have also been noted.

Side effects such as allergic skin reactions, fever and inadequate response to treatment have been observed, but are uncommon.

Your doctor will have more information about unwanted effects of NovoSeven[®] RT.

Tell your doctor or haemophilia nurse as soon as possible if you notice any side effects or do not feel well while you are using NovoSeven[®] RT.

Ask your doctor or haemophilia nurse to answer any questions you have.

Storage

NovoSeven[®] RT must be stored below 25°C. It should not be frozen. NovoSeven[®] RT must only be used if the package is undamaged and the use by ('expiry') date marked on the pack has not passed.

NovoSeven[®] RT should not be stored in syringes. Protect from light.

Never use NovoSeven[®] RT after the expiry date printed on the label and carton.

The expiry date refers to the last day of that month.

Never use NovoSeven[®] RT if the solution is not clear and colourless when reconstituted with the solvent.

Keep out of the reach of children.

Product Description

NovoSeven[®] RT can only be obtained from a hospital or haemophilia treatment centre.

This leaflet does not tell you all that is known about NovoSeven[®] RT. **If you have any questions about NovoSeven[®] RT, ask your doctor or nurse.**

What it looks like

NovoSeven[®] RT is supplied as a white powder, in a glass vial. The powder must be dissolved with the solvent before it is used. The solvent may be supplied in a glass vial or in a pre-filled syringe.

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

Ingredients

The active ingredient in NovoSeven[®] RT is recombinant coagulation factor VIIa (rFVIIa), which is also called eptacog alfa (activated) (btk). NovoSeven[®] RT is made by genetic engineering.

Each vial contains 1.0, 2.0, 5.0 or 8.0 mg (50,000, 100,000, 250,000 or 400,000 IU (International Units)) of rFVIIa. Each vial also contains sodium chloride, calcium chloride dihydrate, sucrose, glycylglycine, polysorbate 80, methionine and mannitol. The solvent syringe contains histidine in water for injections. Sodium hydroxide and hydrochloric acid are used to adjust the pH.

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

Manufacturer

NovoSeven[®] RT is made in Denmark and supplied in Australia by:

Novo Nordisk Pharmaceuticals Pty. Ltd.

Level 3,
21 Solent Circuit,
Baulkham Hills, NSW 2153

NovoSeven[®] RT is supplied in New Zealand by:

Novo Nordisk Pharmaceuticals Ltd.

58 Richard Pearse Drive,
Airport Oaks,
Mangere

NovoSeven[®] is a registered trademark of Novo Nordisk HealthCare AG.

NovoCare[®] is a registered trademark of Novo Nordisk A/S.

This leaflet was prepared on 15 April 2014.

Australian Registration Numbers:

With solvent vial:

AUST R 144160 - 1.0 mg vial

AUST R 144294 - 2.0 mg vial

AUST R 144317 - 5.0 mg vial

AUST R 182324 - 8.0 mg vial

With pre-filled solvent syringe:

AUST R 206194 - 1.0 mg vial

AUST R 206195 - 2.0 mg vial

AUST R 206196 - 5.0 mg vial

AUST R 206197 - 8.0 mg vial

For further information call the NovoCare[®] Customer Care Centre on 1800 668 626 (Australia) or 0800 733 737 (NZ).

www.novonordisk.com.au

www.novonordisk.co.nz

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eptacog alfa (activated) (bhk)

Recombinant coagulation factor VIIa

Instructions For Use

Introduction

READ THESE INSTRUCTIONS CAREFULLY BEFORE USING NOVOSEVEN[®] RT

NovoSeven[®] RT 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[®] 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 infusion 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 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.

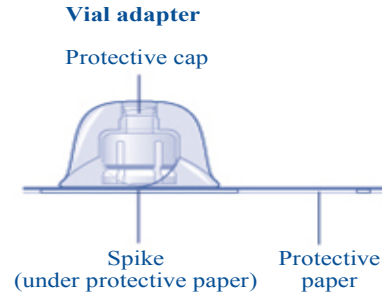
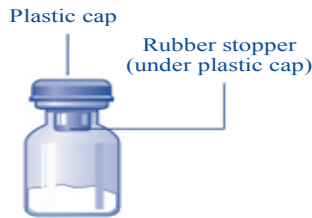
Contents:

The package contains:

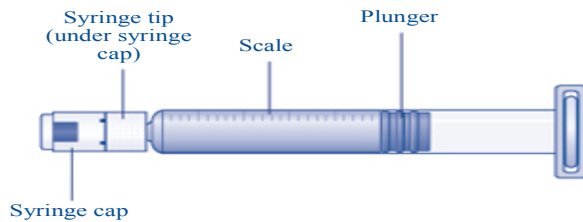
- 1 vial with NovoSeven[®] RT powder
- 1 vial adapter
- 1 pre-filled syringe with solvent
- 1 plunger rod (placed under the syringe)

Overview

Vial with NovoSeven[®] powder



Pre-filled syringe with solvent

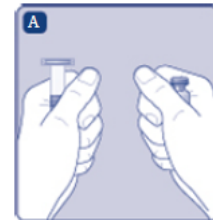


Plunger rod



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 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. 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.

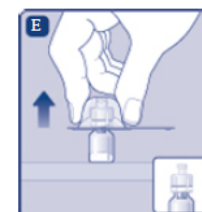


- Place the vial on a flat and solid surface.
- Turn over the protective cap, and snap the vial adapter onto the vial. Once attached, do not remove the vial adapter from the vial.



- Lightly squeeze the protective cap with your thumb and index finger as shown. Remove the protective cap from the vial adapter.

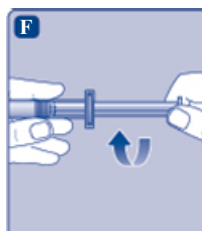
Do not lift the vial adapter from the vial when removing the protective cap.



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.

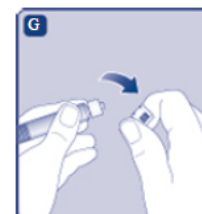
Immediately connect the plunger rod to the syringe by turning it clockwise into the plunger inside the pre-filled syringe until resistance is felt.



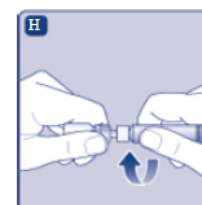
- Remove the syringe cap from the pre-filled syringe by bending it down until the perforation breaks.

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.

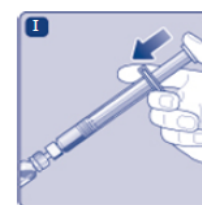


- Screw the pre-filled syringe securely onto the vial adapter until resistance is felt.



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 discoloration, do not use it. Use a new package instead.



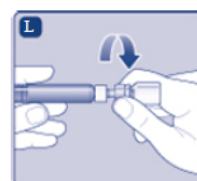
Use the reconstituted NovoSeven® RT at once to avoid infections.

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 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 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.

- **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[®] RT 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[®] RT 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[®] RT 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.