

NovoSeven[®] RT

1.0 mg, 2.0 mg, 5.0 mg and 8.0 mg

eptacog alfa (activated) (btk) Recombinant coagulation factor VIIa

Consumer Medicine Information

What is in this leaflet

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 surgery or hospital.

Reconstitution and injection:

Follow the details instructions on how to inject NovoSeven[®] RT in the instructions for use supplied with the product.

These instructions are also available via the following hyperlinks:

- <http://medsinfo.com.au/media/noinovo7>

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 is supplied 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, glycyglycine, 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 1 mg eptacog alfa (activated).

Manufacturer

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

Novo Nordisk Pharmaceuticals Pty. Ltd.

Level 10,

118 Mount Street,

North Sydney, NSW 2060

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

Novo Nordisk Pharmaceuticals Ltd.

11-19 Customs Street West,

Commercial Bay Tower,

Level 18, Office 1834,

Auckland 1010

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

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

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Australian Registration Numbers:

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

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