

NovoSeven[®] RT

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using NovoSeven[®] RT?

NovoSeven[®] RT contains the active ingredient eptacog alfa (activated) (bhk). NovoSeven[®] RT is used to control bleeding episodes and to prevent excess bleeding connected with surgery in people with certain blood clotting disorders. For more information, see Section [1. Why am I using NovoSeven[®] RT?](#) in the full CMI.

2. What should I know before I use NovoSeven[®] RT?

Do not use it if you have ever had an allergic reaction to NovoSeven[®] RT or any of the ingredients listed at the end of the CMI, are allergic to mice, hamster or cow proteins (such as cow's milk).

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use NovoSeven[®] RT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NovoSeven[®] RT and affect how it works.

For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use NovoSeven[®] RT?

Follow your doctor's instructions, including your exact dose and dosing schedule.

NovoSeven[®] RT is for intravenous injection, and requires mixing the powder in the vial with the solvent supplied in the syringe before use.

More instructions can be found in Section [4. How do I use NovoSeven[®] RT?](#) in the full CMI.

5. What should I know while using NovoSeven[®] RT?

Things you should do	- Remind any doctor, dentist or pharmacist you visit that you are using NovoSeven[®] RT - With your doctor, monitor bleeding carefully, and notify them if your bleeding gets worse.
Things you should not do	- Do not inject yourself without proper training from your doctor or haemophilia nurse - Do not stop using NovoSeven[®] RT or change the dose without consulting your doctor.
Driving or using machines	There is no specific information on the use of NovoSeven[®] RT and driving or using machines.
Drinking alcohol	There is no specific information on any possible interactions of NovoSeven[®] RT with alcohol.
Looking after your medicine	- Store NovoSeven[®] RT below 25°C. Do not allow the medicine to freeze. Protect from light. - Do not store it in a syringe.

For more information, see Section [5. What should I know while using NovoSeven[®] RT?](#) in the full CMI.

6. Are there any side effects?

Contact your doctor or go to hospital if you experience symptoms of clotting, such as sudden pain or discomfort in the chest or abdomen, or pain, redness, swelling or heat in an arm or leg; likewise, if you experience symptoms of a serious allergic reaction, such as widespread skin rash, shortness of breath, wheezing, swelling of the face, lips or tongue.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

NovoSeven® RT

Active ingredient: *eptacog alfa (activated)* (bhk)

Consumer Medicine Information (CMI)

This leaflet provides important information about using NovoSeven® RT. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using NovoSeven® RT.**

Where to find information in this leaflet:

1. [Why am I using NovoSeven® RT?](#)
2. [What should I know before I use NovoSeven® RT?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use NovoSeven® RT?](#)
5. [What should I know while using NovoSeven® RT?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using NovoSeven® RT?

NovoSeven® RT contains the active ingredient eptacog alfa (activated), which is recombinant coagulation factor VIIa (rFVIIa).

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.

2. What should I know before I use NovoSeven® RT?

Warnings

Do not use NovoSeven® RT if you:

- have an allergy to mice, hamster or cow proteins (such as cows' milk);
- are allergic to eptacog alfa (activated) or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have recently had, or are planning to have surgery
- have had a crush injury
- are prone to disseminated intravascular coagulation (DIC), a condition where blood clots develop throughout the blood stream). You must be carefully monitored.

- have a serious blood infection
- have an increased risk of blood clots (thrombosis) or advanced hardening of the arteries with cholesterol deposits
- have or have had coronary artery disease or previous heart attack
- have liver disease
- are allergic to platelets or blood products
- have a genetic condition that affects your ability to digest sugars (fructose, sucrose, glucose or maltose)
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. They will discuss the risks and benefits of using NovoSeven® RT during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. They can discuss with you the risks and benefits to you and your baby.

3. What if I am taking other medicines?

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

Do not use NovoSeven® RT at the same time as prothrombin complex concentrates or recombinant factor XIII (13), medicines used to help with blood clotting.

Check with your doctor if you:

- take coagulation factor concentrates
- take medicines called antifibrinolytic drugs (such as tranexamic acid) which are also used to control bleeding.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect NovoSeven® RT.

4. How do I use NovoSeven® RT?

How much to use

- Your doctor will determine the amount required and how frequently you need it based on the condition being treated, weight and other relevant factors.
- Follow the instructions provided and use NovoSeven® RT until your doctor tells you to stop.

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

When to use NovoSeven® RT

- The first dose should be given as early as possible after bleeding has started.
- NovoSeven® RT should be used according to your doctor's clinical assessment.

How to use NovoSeven® RT

- NovoSeven® RT is given as an injection into a vein (intravenously) over a period of 2 - 5 minutes.
- The solvent must be added (reconstitution) to the vial of NovoSeven® RT powder before the solution is injected. The solution should be clear and colourless.
- Do not inject the reconstituted medicine if the solution is **not** clear and colourless or it has anything floating in it.
- Do not use the equipment required to inject yourself if it has been dropped or it has been damaged
- 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.
- Do not inject yourself without proper training from your doctor or haemophilia nurse.

Reconstitution and injection:

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

These instructions are also available via the following hyperlink:

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

- NovoSeven® RT is for single use in one person only.
- Reconstituted NovoSeven® RT should be used immediately. Discard your vial after use.

After injection

Do not refill NovoSeven® RT vials.

Follow general precautionary measures for removal and disposal of needles to eliminate the risk of needlestick injury.

If you forget to use NovoSeven® RT

You should contact your doctor as soon as possible so that they may take the appropriate action.

If you use too much NovoSeven® RT

If you are given or if you give yourself too much NovoSeven® RT

You should immediately:

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using NovoSeven® RT?

Things you should do

Continue using NovoSeven® RT for as long as your doctor tells you.

You and your doctor should monitor your bleeding.

Call your doctor straight away if your bleeding is not controlled. If you are injecting NovoSeven® RT at home and your bleeding is not controlled within 24 hours, you will need hospital care.

Remind any doctor, dentist or pharmacist or other health professionals you visit that you are using NovoSeven® RT.

Things you should not do

- Do not stop using NovoSeven® RT without consulting your doctor
- Do not change the dose or schedule without consulting your doctor
- Do not continue home treatment for longer than 24 hours. If bleeding is not controlled within 24 hours, contact your doctor as soon as possible
- Do not give NovoSeven® RT to anyone else, even if they have the same condition as you
- Do not share needles, syringes, or other injecting equipment with anyone
- Do not use NovoSeven® RT to treat any other complaints.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how NovoSeven® RT affects you.

There is no specific information on the use of NovoSeven® RT and driving.

Drinking alcohol

Tell your doctor if you drink alcohol.

There is no specific information on any possible interactions of NovoSeven® RT with alcohol.

Looking after your medicine

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place below 25°C, away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Do not freeze.

Protect from light.

Do not store NovoSeven® RT in a syringe.

If you cannot use the reconstituted solution immediately, keep it in the vial in a refrigerator (2 °C - 8 °C) and use it within 24 hours.

Keep it where young children cannot reach it.

When to discard your medicine

Do not use NovoSeven® RT after the expiry date. The expiry date refers to the last day of that month.

Discard your medicine once the permitted storage time listed in "Looking after your medicine" has passed.

Discard any solution left in the vial after you have taken the dose recommended by your doctor for your injection.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Skin-related: - rash, itching or hives Other: - nausea (feeling sick) - headache - fever - changes in some liver function and blood tests - reactions including pain where the injection is given.	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Allergic reactions (hypersensitivity) including anaphylaxis: - difficulty swallowing or breathing - shortness of breath or wheezing - a feeling of pressure and tightness in the rib cage (chest) - redness and/or swelling of the lips, tongue, face or hands - generalised itching, widespread rash, hives and weals - pale and cold skin, fast heartbeat, or dizziness (low blood pressure) - headache, nausea or vomiting Blood-related: - Blood clots in arteries in the heart (which could lead to a	Stop the injection immediately if you have an allergic reaction. Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
heart attack or angina), in the brain (which could lead to a stroke) or in the intestine and kidneys. Signs may include severe pain in the chest, breathlessness, confusion, difficulty with speech or movement (paralysis) or abdominal pain. - Blood clots in the veins in lungs, legs, liver, kidneys or at the site of injection. Signs may include difficulty in breathing, red and painful swelling in the leg and abdominal pain. - Bleeding is not well controlled.	

Tell your doctor, haemophilia nurse or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems in Australia. If you are in New Zealand, you can report side effects at <https://nzphvc.otago.ac.nz/reporting/>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor, haemophilia nurse or pharmacist before you decide to stop taking any of your medicines.

7. Product details

What NovoSeven® RT contains

Active ingredient (main ingredient)	eptacog alfa (activated) (bhk)
Other ingredients (inactive ingredients)	Powder vial - sodium chloride - calcium chloride dihydrate - sucrose - glycylglycine - polysorbate 80 - methionine - mannitol. Solvent syringe - histidine - water for injections - sodium hydroxide and hydrochloric acid to adjust the pH.

Potential allergens	N/A
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Do not take this medicine if you are allergic to any of these ingredients.

What NovoSeven® RT 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.

Each pack also contains a vial adapter to help with mixing the powder and solvent, and a syringe plunger rod.

NovoSeven® RT is available in single packs with single-dose vials of:

1.0 mg vial: AUST R 206194

2.0 mg vial AUST R 206195

5.0 mg vial: AUST R 206196

8.0 mg vial: AUST R 206197.

Who distributes NovoSeven® RT?

NovoSeven® RT is supplied in Australia by:

Novo Nordisk Pharmaceuticals Pty Ltd

Level 10

118 Mount Street

North Sydney NSW 2060

Australia

NovoSeven® RT is supplied in New Zealand by:

Novo Nordisk Pharmaceuticals Ltd.

PO Box 51-268

Pakuranga

Auckland

New Zealand

Further information

For further information call Novo Nordisk Medical Information on 1800 668 626 (Australia) or 0800 733 737 (New Zealand).

www.novonordisk.com.au

www.novonordisk.co.nz

Always check the following websites to ensure you are reading the most recent version of the NovoSeven® RT Consumer Medicine Information:

- www.novonordisk.com.au

- <https://www.ebs.tga.gov.au/>

- <https://www.novonordisk.co.nz/>

- <https://www.medsafe.govt.nz/>

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