

# NovoSeven<sup>®</sup> RT 1.0mg

# NovoSeven<sup>®</sup> RT 2.0mg

# NovoSeven<sup>®</sup> RT 5.0mg

eptacog alfa (activated) (bhk)  
Recombinant coagulation factor VIIa  
**Consumer Medicine Information**

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This leaflet answers some common questions about NovoSeven<sup>®</sup> RT. It does not contain all the available information. It does not take the place of talking to your doctor or health care professional.

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

**If you have any concerns about using this medicine, ask your doctor or health care professional. Keep this leaflet with the medicine.** You may need to read it again.

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## What NovoSeven<sup>®</sup> RT is used for

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NovoSeven<sup>®</sup> 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 in human blood. NovoSeven<sup>®</sup> RT is made by genetic engineering.

NovoSeven<sup>®</sup> 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 have prescribed NovoSeven<sup>®</sup> RT for another reason.

**Ask your doctor or health care professional if you have any questions about why NovoSeven<sup>®</sup> RT has been given to you.**

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## Before you use NovoSeven<sup>®</sup> RT

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### ***When NovoSeven<sup>®</sup> RT should not be used***

You should not use or be treated with NovoSeven<sup>®</sup> RT if you have an allergy to:

- mice, hamsters or cattle
- NovoSeven<sup>®</sup> 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<sup>®</sup> 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 cattle;
- have had a reaction to any of the ingredients in NovoSeven<sup>®</sup> 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.

**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<sup>®</sup> RT.**

### ***Taking other medicines***

**Tell your doctor if you are using or taking any:**

- blood clotting factors;
- blood products.

**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 is not damaged.

**Do not use NovoSeven® RT if any of these happen.**

Each vial of NovoSeven® RT is for your personal use only.

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## **Using NovoSeven® RT**

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### ***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:**

If you are reconstituting your own NovoSeven® RT you must follow the reconstitution technique below, as demonstrated by your doctor or nurse.

Always use aseptic technique (e.g. wash your hands before use,

etc.) and follow your health care professional's instructions.

You will need a sterile syringe, sterile needles in addition to the vials of NovoSeven® RT and solvent.

1. Remove the protective plastic cap from the NovoSeven® RT powder vial and solvent vial, as shown to you by your doctor or nurse.
2. Clean the stoppers with an alcohol swab and allow to dry before use.
3. Attach the transfer needle to the disposable syringe and then remove the protective needle cover.
4. Withdraw the correct volume of solvent from the container. The volume required is the same amount in the solvent vial.
5. Insert the needle through the centre of the stopper into the NovoSeven® RT powder vial and slowly inject the solvent. (The powder does not contain a vacuum).
6. Gently swirl until all material is dissolved.

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.

### ***How to use NovoSeven® RT in a syringe***

NovoSeven® RT will be injected intravenously by your doctor or nurse, or by yourself (after proper instruction given by a healthcare professional). It may be several times a day. If you are injecting the NovoSeven® RT, you must follow the administration technique below, as demonstrated by your doctor or nurse.

**To inject NovoSeven® RT with a syringe:**

- Draw back the plunger (to the same volume as you are going to inject) to admit air into the syringe.
- Insert the needle into the vial containing the reconstituted NovoSeven® RT.
- Inject air into the vial and then withdraw the reconstituted NovoSeven® RT into the syringe.
- Remove and discard the transfer needle.
- Attach a suitable intravenous injection needle and inject slowly as shown to you by your doctor or nurse.
- Discard the used needle and syringe safely in an appropriate waste container (e.g. yellow plastic sharps bin).

### ***After you use it***

- Do not refill NovoSeven® RT vials.
- Health care 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.**

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## **While you are using NovoSeven® RT**

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### ***If you forget to use it***

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

### ***Things you must do***

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

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### **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 kept under control, hospital care may be necessary.

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### **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 rash, itching, fever, 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 leading to heart attacks, ischaemic stroke, and pulmonary embolism (i.e., blockage of a blood vessel in the lungs) have occurred on very rare occasions in patients who are predisposed to these conditions.

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.**

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### **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.**

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

**Keep out of the reach of children**

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### **Disposal**

Any NovoSeven® RT that is not used 6 hours after being dissolved should be disposed of safely in an appropriate waste container.

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### **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.

#### **Ingredients**

The active ingredient in NovoSeven® RT is recombinant coagulation factor VIIa

(rFVIIa), which is also called eptacog alfa (activated) (bhk). NovoSeven® RT is made by genetic engineering. Each vial contains 1.0, 2.0 or 5.0 mg of rFVIIa.

Each vial also contains sodium chloride, calcium chloride, glycyglycine, polysorbate 80 and mannitol. The solvent vial contains histidine in water for injections.

#### **Manufacturer**

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

**Novo Nordisk Pharmaceuticals Pty. Ltd.**

A.B.N. 40 002 879 996  
Level 3  
21 Solent Circuit  
Baulkham Hills NSW 2153

This leaflet was prepared on  
19 Aug 2008

Australian Registration Numbers:  
AUST R 144160 - 1.0mg vial  
AUST R 144294 - 2.0mg vial  
AUST R 144317 - 5.0mg vial

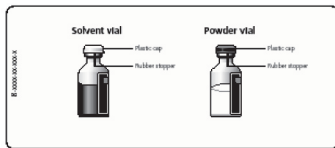
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For further information call the NovoCare Customer Care Centre on 1800 668 626.

[www.novonordisk.com.au](http://www.novonordisk.com.au)

# NovoSeven® RT User Instructions



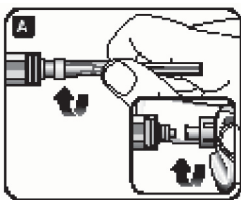
## Preparing the solution

Wash your hands. NovoSeven® RT powder and solvent vials should be at room temperature at reconstitution. 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 alcohol swabs and allow them to dry before use.

Use a disposable syringe of an appropriate size and a vial adapter, transfer needle (20 - 26G) or other suitable device.

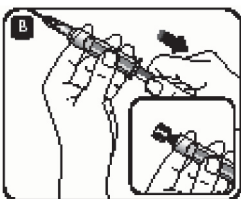
### A

Attach the vial adapter or needle to the syringe.



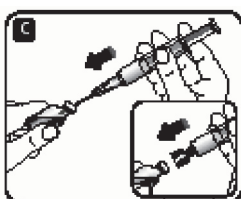
### B

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



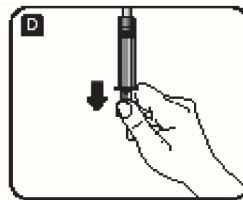
### C

Click the vial adapter onto the solvent vial or insert the needle into the rubber stopper of the solvent vial. To inject the air into the vial, push the plunger until you feel a clear resistance.



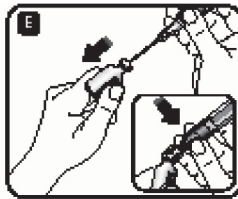
### D

Hold the syringe with the solvent vial upside down. If you are using a transfer needle, make sure that the needle tip is in the solvent. Pull the plunger to draw the solvent into the syringe.



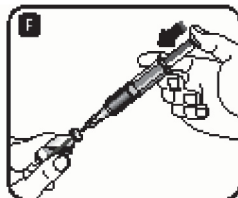
### E

Remove the empty solvent vial. If you use a vial adapter, tip the syringe to remove it from the vial.



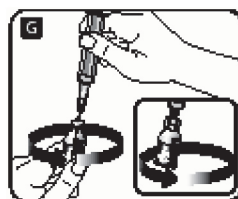
### F

Attach the syringe with vial adapter or transfer needle to the powder vial. If you use a transfer needle, make sure to penetrate the centre of the rubber stopper. Hold the syringe slightly tilted with the vial facing downwards. Push the plunger slowly to inject the solvent into the powder vial. Make sure not to aim the stream of solvent directly at the NovoSeven® RT 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 discoloration. If you notice either, do not use it. NovoSeven® RT reconstituted product is a clear, colourless solution. Keep the vial adapter or needle attached to the vial.



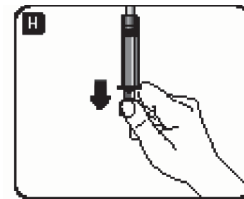
Although NovoSeven® RT will be stable for 24 hours after it has been mixed, you should use it at once to avoid infection. If you do not use it immediately after mixing, you should store the vial with the syringe still attached in a refrigerator at 2°C to 8°C

for no longer than 24 hours. Do not store the solution without your doctor's advice.

## Injecting the solution

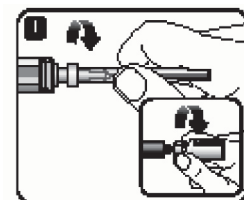
### H

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). If you use a transfer needle, make sure that the needle tip is in the solution. Hold the syringe with the vial upside down and pull the plunger to draw all the solution into the syringe.



### I

If you use a vial adapter, unscrew the vial adapter with the empty vial. If you use a transfer needle, remove the transfer needle from the vial, replace the needle cap, and twist the needle off the syringe. NovoSeven® RT is now ready for injection. Follow the injection procedure as instructed by your health care professional.



### J

Safely dispose of the syringe, vials, any unused product and other waste materials as instructed by your health care professional.

