

# NovoSeven<sup>®</sup> RT

**1.0 mg, 2.0 mg, 5.0 mg and 8.0 mg**

*eptacog alfa (activated) (bhk)*

*Recombinant coagulation factor VIIa*

---

## Instructions For Use

---

### *Introduction*

#### **READ THESE INSTRUCTIONS CAREFULLY BEFORE USING NOVOSEVEN<sup>®</sup> RT**

NovoSeven<sup>®</sup> 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<sup>®</sup> RT must be injected into your vein (intravenous injection). The equipment in this package is designed to reconstitute and inject NovoSeven<sup>®</sup> RT.

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<sup>®</sup> 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.

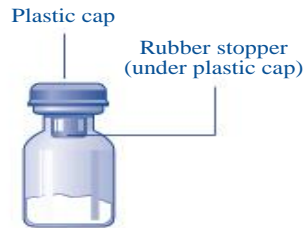
### *Contents:*

The package contains:

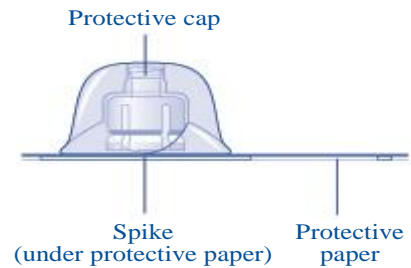
- 1 vial with NovoSeven<sup>®</sup> RT powder
- 1 vial adapter
- 1 pre-filled syringe with solvent
- 1 plunger rod (placed under the syringe)

## Overview

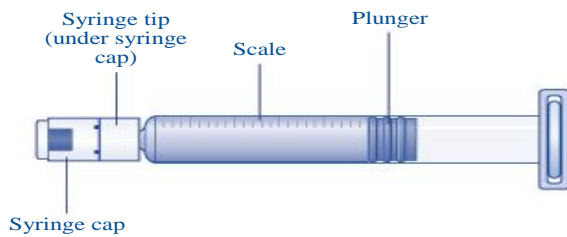
### Vial with NovoSeven<sup>®</sup> powder



### Vial adapter



### Pre-filled syringe with solvent

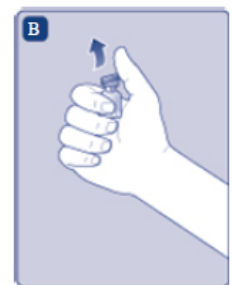
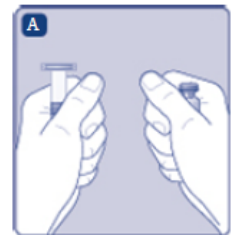


### Plunger rod



## 1. Prepare the vial and the syringe

- Take out the number of NovoSeven<sup>®</sup> 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.

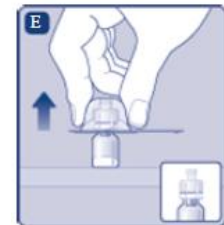


- Place the vial on a flat and solid surface.
- Turn over the protective cap, and snap the vial adapter onto the vial. Once attached, do not remove the vial adapter from the vial.



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

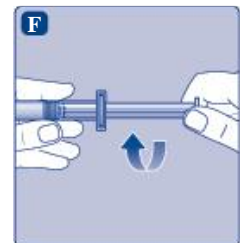
Do not lift the vial adapter from the vial when removing the protective cap.



### 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.

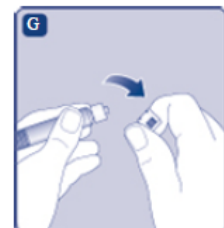
**Immediately** connect the plunger rod to the syringe by turning it clockwise into the plunger inside the pre-filled syringe until resistance is felt.



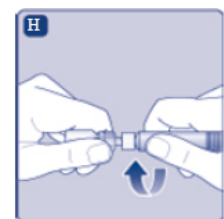
- Remove the syringe cap from the pre-filled syringe by bending it down until the perforation breaks.

**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.**

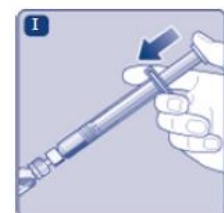


- Screw the pre-filled syringe securely onto the vial adapter until resistance is felt.



### 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.**  
**If NovoSeven® RT is reconstituted and stored in a polypropylene syringe, it is recommended to use an in-line filter with a pore size of 25 micrometers upon administration.**
- **Check the reconstituted solution.** It must be colourless. **If you notice visible particles or discoloration, do not use it.** Use a new package instead.

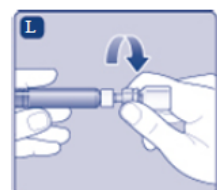


**Use the reconstituted NovoSeven® RT at once** to avoid infections.

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.**