



EUROPEAN MEDICINES AGENCY  
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## NovoSeven (*eptacog alfa*)

An overview of NovoSeven and why it is authorised in the EU

### What is NovoSeven and what is it used for?

NovoSeven is a medicine used to treat bleeding episodes and to prevent bleeding after surgical procedures. It is used in patients with the following conditions:

- congenital haemophilia (a bleeding disorder present from birth) who have developed or are expected to develop 'inhibitors' (antibodies) against factor VIII or IX;
- acquired haemophilia (a bleeding disease caused by the development of inhibitors to factor VIII);
- congenital factor VII deficiency;
- Glanzmann's thrombasthenia (a rare bleeding disorder), who cannot be treated with a transfusion of platelets (components that help the blood to clot).

The medicine is also used to treat patients with severe postpartum haemorrhage (serious bleeding after giving birth), when medicines that stimulate the muscles of the womb to contract (uterotonic medicines) are not effective at controlling the bleeding.

NovoSeven contains the active substance eptacog alfa.

### How is NovoSeven used?

NovoSeven can only be obtained with a prescription. When used to treat bleeding episodes or prevent bleeding after surgery, treatment should be started under the supervision of a doctor who has experience in the treatment of haemophilia or bleeding disorders.

The medicine is available as a powder and solvent that are made up into a solution to be injected into a vein. The dose depends on the patient's condition and body weight and the type of bleed.

Patients or carers may be able to give NovoSeven themselves after suitable training. For more information about using NovoSeven, see the package leaflet or contact your doctor or pharmacist.

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## **How does NovoSeven work?**

The active substance in NovoSeven, eptacog alfa, is almost identical to a human protein called factor VII and works in the same way. In the body, factor VII is involved in blood clotting. It activates another factor called factor X, which starts the clotting process at the site of the bleed. By activating factor X, NovoSeven is able to help control the bleeding when the body's own clotting factors are reduced, absent, or not working properly.

Because factor VII acts directly on factor X, independently from factors VIII and IX, NovoSeven can be used in patients with haemophilia who have developed inhibitors to factor VIII or IX. NovoSeven can also be used to replace the missing factor VII in patients with factor VII deficiency.

## **What benefits of NovoSeven have been shown in studies?**

NovoSeven has been studied in patients with haemophilia and in patients with factor VII deficiency. The main measure of effectiveness was the number of bleeding episodes that were controlled effectively.

In a study involving 61 patients with haemophilia who had developed inhibitors, 84% of the 57 serious bleeds and 59% of the 38 surgical bleeds were controlled effectively with NovoSeven. In another study in 60 patients with mild to moderate bleeding episodes, which investigated whether NovoSeven could be used in the home setting, 90% of the bleeding episodes were controlled effectively.

Data on the use of NovoSeven in patients with Glanzmann's thrombasthenia were obtained from a registry of patients treated with the medicine, which showed that treatment with NovoSeven was successful in 79% of the bleeding episodes (262 out of 333) and 88% of the surgeries (140 out of 159).

NovoSeven has also been studied in patients with severe postpartum haemorrhage. When given together with standard care, the medicine was found to be more effective than standard care alone at controlling bleeding, measured by the need for surgical treatment to block or tie a bleeding blood vessel (embolisation or ligation) to stop the bleeding. In a study involving 84 women with severe postpartum haemorrhage whose bleeding could not be controlled with a uterotonic medicine, 50% (21 out of 42) of women treated with NovoSeven together with standard care needed embolisation and/or ligation to stop the bleeding compared with 83% (35 out of 42) of those given standard care alone.

## **What are the risks associated with NovoSeven?**

The most common side effects with NovoSeven (which may affect up to 1 in 100 patients) are venous thromboembolic events (problems caused by blood clots in the veins), rash, pruritus (itching), urticaria (hives), fever and reduced effectiveness of treatment.

NovoSeven must not be used in people who are hypersensitive (allergic) to eptacog alfa, to mouse, hamster or cow proteins, or to any of the other ingredients.

For the full list of side effects and restrictions, see the package leaflet.

## **Why is NovoSeven authorised in the EU?**

In patients with bleeding disorders, NovoSeven has been shown to be effective at preventing and controlling bleeding episodes, including after surgery. In women experiencing severe postpartum haemorrhage that cannot be effectively controlled by uterotonic medicines, NovoSeven reduces the

need for surgical procedures to control the bleeding. The European Medicines Agency therefore decided that NovoSeven's benefits are greater than its risks and it can be authorised in the EU.

### **What measures are being taken to ensure the safe and effective use of NovoSeven?**

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of NovoSeven have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of NovoSeven are continuously monitored. Side effects reported with NovoSeven are carefully evaluated and any necessary action taken to protect patients.

### **Other information about NovoSeven**

NovoSeven received a marketing authorisation valid throughout the EU on 23 February 1996.

Further information on NovoSeven can be found on the Agency's website:  
[ema.europa.eu/medicines/human/EPAR/novoseven](http://ema.europa.eu/medicines/human/EPAR/novoseven).

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