Indications and Usage
NovoSeven® RT (Coagulation Factor VIIa [Recombinant]) is used for:

- Treatment of bleeding and prevention of bleeding for surgeries and procedures in adults and children with hemophilia A or B with inhibitors, congenital Factor VII (FVII) deficiency, and people with Glanzmann's thrombasthenia who have a decreased or absent response to platelet transfusions
- Treatment of bleeding and prevention of bleeding for surgeries and procedures in adults with acquired hemophilia

Selected Important Safety Information

WARNING: BLOOD CLOTS

- Serious blood clots that form in veins and arteries with the use of NovoSeven® RT have been reported.
- Your healthcare provider should discuss the risks and explain the signs and symptoms of blood clots to you. Some signs of a blood clot may include pain, swelling, warmth, redness, or a lump in your legs or arms, chest pain, shortness of breath, or sudden severe headache and/or loss of consciousness or function.
- Your healthcare provider should monitor you for blood clots during treatment with NovoSeven® RT.

Please see additional Important Safety Information, including Boxed Warning, throughout. Please click here for Prescribing Information or visit NovoSevenRT.com.
What is Congenital Factor VII Deficiency?

Congenital factor VII deficiency is a bleeding disorder in which there are low levels of factor VII in the blood. When there is not enough factor VII in the blood, clotting can take much longer than normal or may not occur at all.

- Factor VII deficiency is rare, affecting about 1 in every 500,000 people
- Mild factor VII deficiency is mostly associated with little to no symptoms. However, it can be associated with increased bleeding after surgery or trauma
- Moderate factor VII deficiency is associated with minor spontaneous bleeding
- Severe factor VII deficiency is marked by spontaneous, severe, and even life-threatening bleeding

Congenital factor VII deficiency is caused by an abnormal gene that is inherited from both parents. Men and women have equal chances of being born with factor VII deficiency. Factor VII deficiency can also occur in someone who wasn’t born with it, due to a variety of causes. This is called acquired factor VII deficiency.

Signs and symptoms of congenital factor VII deficiency

- Frequent nosebleeds
- Easy bruising
- Bleeding from the gums
- Heavy, prolonged menstrual bleeding in women
- Muscle and joint bleeds
- Intestinal bleeding
- Head bleeds in newborns
- Prolonged bleeding following surgery

Available treatments

- Fresh frozen plasma (FFP)
- Recombinant activated factor VII concentrate (rFVIIa)

Factor VII deficiency can be detected at birth. However, some people with mild deficiency grow into adulthood without knowing they have it.

Important Safety Information (cont’d)

Warnings and Precautions

- NovoSeven® RT should be used with caution if you have an increased risk for blood clots, such as with disseminated intravascular coagulation (DIC), clogged arteries, crush injury, septicemia (an infection in the blood), uncontrolled bleeding after giving birth, history of heart disease, liver disease, limited movement following surgery, in elderly people, in newborns, or if you are taking aPCCs/PCCs (activated or nonactivated prothrombin complex concentrates) with NovoSeven® RT.

Rooted in Effective Bleed Control

Helping people with bleeding disorders is ingrained in the history of NovoSeven® RT.

Experience: 30 years of research and long-term clinical experience

Effectiveness: Proven effective for more bleeding disorders than any other product

Portability: Room temperature stable for fast access to treatment

Speed: Fast to mix, fast to infuse

Safety: Low rate of thrombotic adverse events (blood clots)

*Clinical trial on compassionate use, also known as expanded access, began enrolling in 1989; FDA approval received in 1999.
Rely on the **Proven Efficacy** of NovoSeven® RT

**Effective in stopping nonsurgical and surgical bleeds**

93% (N=70a)

*Rely on the Proven Efficacy of NovoSeven® RT*  

NovoSeven® RT is compact and can be kept at room temperature (≤77°F) for up to 3 years from the date it is manufactured. This way you can travel without refrigerating NovoSeven® RT.

After mixing, NovoSeven® RT may be stored at room temperature in the vial (or refrigerated) for up to 3 hours.

**Ready-to-Travel Case**

A portable, reusable travel case makes storing supplies easy, at home or while traveling. Visit the Resources section of NovoSevenRT.com to get a Ready-to-Travel case.

**Important Safety Information (cont’d)**

**Warnings and Precautions**

- Allergic reactions, including serious whole body allergic reactions, have been reported with NovoSeven® RT. Tell your healthcare provider if you are allergic to NovoSeven® RT, any of its ingredients, or mice, hamsters, or cows. If you think you are having an allergic reaction, call your healthcare provider right away. Some signs of allergic reaction may include shortness of breath, rash, itching, redness of the skin, and fainting/dizziness.

- People with Factor VII deficiency should be monitored by their healthcare provider for antibodies, which can cause NovoSeven® RT to stop working properly.

**Important Safety Information (cont’d)**

**Side Effects**

- The most common and serious side effects are blood clots.
- Tell your healthcare provider about any side effects that bother you or do not go away.

Please see additional Important Safety Information, including Boxed Warning, throughout. Please click here for Prescribing Information or visit NovoSevenRT.com.
Stopping bleeds quickly is important. The faster you infuse treatment, the sooner it can start to work.

**NovoSeven® RT with MixPro® is fast to mix**
- Prefilled syringe means no extra steps to fill a syringe with diluent

Visit [NovoSevenRT.com](http://NovoSevenRT.com) to find a local Novo Nordisk Representative and request a Patient Starter Kit.

**Infusion**
- NovoSeven® RT is given as an intravenous (IV) bolus injection
- NovoSeven® RT provides low infusion volume
- Infusing NovoSeven® RT takes only 2 to 5 minutes

**NovoSeven® RT**
15-30 mcg/kg
2-5 minutes

**Established Safety Profile**

Recombinant manufacturing minimizes the possibility of viral contamination
- Made without any human blood or plasma

The safety of NovoSeven® RT is well studied
- Works at the site of injury
- Low rate of thrombotic adverse events (blood clots) in clinical studies

**Important Safety Information (cont’d)**

Use with Other Drugs
- Blood clots may occur if NovoSeven® RT is given with Coagulation Factor XIII (13).

Warnings and Precautions
- People with Factor VII deficiency should be monitored by their healthcare provider for antibodies, which can cause NovoSeven® RT to stop working properly.

You can learn more about NovoSeven® RT for congenital factor VII deficiency by speaking with your doctor and by visiting [NovoSevenRT.com](http://NovoSevenRT.com).

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Please click here for Prescribing Information or visit NovoSevenRT.com.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

NovoSeven® RT is a prescription medication. Novo Nordisk provides patient assistance for those who qualify. Please call 1-877-NOVO-777 (1-877-668-6777) to learn more about Novo Nordisk assistance programs.

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