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 hemophilia?

Hemophilia is a bleeding disorder that prevents blood from clotting properly. Normally, when a person starts bleeding, proteins in blood (called clotting factors) work together to form clots and stop the bleeding.

People with hemophilia are either missing or have a reduced amount of a particular clotting factor, so they may need special treatment (replacement clotting factor) to help their blood clot. Patients with hemophilia A or B need factor VIII or factor IX, respectively.

What are inhibitors?

Inhibitors are a potential concern for people with hemophilia who are receiving replacement clotting factor treatment to control bleeds. Sometimes, when a person receives treatment to help their blood clot, the body thinks that the treatment is something foreign and harmful. When this happens, the body develops antibodies—inhibitors—that attack the replacement factor used for hemophilia treatment. These antibodies prevent the replacement clotting factor from working properly.

It is important to know that this doesn’t happen to everyone. Only about 20%-30% of people with severe or moderately severe hemophilia A and less than 5% of those with hemophilia B develop inhibitors.

Those who develop inhibitors need a different type of treatment to control bleeds.

For people with congenital hemophilia A or B with inhibitors (CHwI) it's time to Spread Your Wings

Chase, 5 years old, lives with CHwI, and loves anything that has to do with cars, planes, or playing golf.

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, and fast to control bleeds
Safety: Low rate of thrombotic adverse events (blood clots)

*Compassionate use, also known as expanded access, began enrolling in 1989; FDA approval received in 1999.

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.
- 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.

Please see additional Important Safety Information, including Boxed Warning, throughout. Please click here for Prescribing Information or visit NovoSevenRT.com.
Rely on the **Proven Efficacy of NovoSeven® RT**

Muscle bleeds

- 86%

Joint bleeds

- 91%

**NovoSeven® RT is Room Temperature Stable and Travel Ready**

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](http://NovoSevenRT.com) to get a Ready-to-Travel case.

**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.

**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.

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Stopping bleeds quickly is important. The faster you infuse treatment, the sooner it can start to work.

**Infusion**
- NovoSeven® RT is given as an intravenous (IV) bolus injection
- NovoSeven® RT has 16x less infusion volume than plasma-derived activated prothrombin complex concentrate (pd-aPCC)a,b

*aIn patients with hemophilia A or B with inhibitors.
*bIndividual doses for a joint bleed are compared and based on an 88-kg (194-lb) person.

NovoSeven® RT
90 mcg/kg
8 mL

pd-aPCC
75 U/kg
132 mL

Infusing NovoSeven® RT takes only 2 to 5 minutes
NovoSeven® RT is up to 18x faster to infuse than pd-aPCCc

cIndividual doses for a joint bleed are compared and based on an 88-kg (194-lb) person.

**Redosing**
NovoSeven® RT can be redosed every 2 hours.a This lets you dose as needed to get bleeds under control fast.

Your Hemophilia Treatment Center (HTC) and your doctor will help you decide what dosing schedule is best for you.

*aIn patients with hemophilia A or B with inhibitors.

**Recombinant manufacturing minimizes the possibility of viral contamination**
- NovoSeven® RT is the only recombinant bypassing agent for hemophilia with inhibitors
- Made without any human blood or plasma

**The safety of NovoSeven® RT is well studied**
- Works at the site of injury
- <1% rate of thrombotic adverse events (blood clots) in clinical trials

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

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

**You can learn more about NovoSeven® RT for CHwI by speaking with your doctor and by visiting NovoSevenRT.com.**
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Use with Other Drugs
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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.

Novo Nordisk Inc., 800 Scudders Mill Road, Plainsboro, New Jersey 08536 U.S.A.

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