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.
What is Glanzmann’s thrombasthenia (GT)?

Glanzmann’s thrombasthenia is a rare genetic disorder that affects about 1 in 1 million people. It is inherited from both parents and can occur in both men and women.

Your blood contains small cells called platelets. When you cut or injure a blood vessel and begin to bleed, platelets rush to the injury site and clump together to help stop the bleeding. Numerous proteins on the platelets help them work properly. Some of these proteins are called glycoproteins.

People with GT have a certain kind of glycoprotein on their platelets that is decreased or defective due to a genetic mutation. This prevents platelets from forming a plug to stop bleeding.

Signs and symptoms of GT
Those with GT mainly have skin and mucous membrane types of bleeding. The most common signs of GT include:
• Easy bruising
• Bleeding from the nose or gums
• Heavy menstruation (in women)

A common treatment for GT is platelet transfusion, but some patients become resistant to this treatment and need a different approach.

GT is a serious condition and bleeding can be unpredictable, so having effective treatment is important.

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)

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.
NovoSeven® RT: Proven Effective in a Majority of GT-Related Bleeds

Effectiveness seen in a prospective, observational, multinational study

Bleeding episodes

94% (n=92; 266 bleeding events)

Surgical procedures

99% (n=77; 160 procedures)

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.

NovoSeven® RT is Room Temperature Stable and Travel Ready

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)

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

**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

**Visit NovoSevenRT.com to find a local Novo Nordisk Representative and request a Patient Starter Kit.**

**NovoSeven® RT**
- 90 mcg/kg
- 2-5 minutes

**Established Safety Profile**

**Recombinant manufacturing minimizes the possibility of viral contamination**
- NovoSeven® RT is the only recombinant therapy indicated for GT
- Made without any human blood or plasma
  - In patients with refractoriness to platelet transfusions, with or without antibodies to platelets.

**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).

**You can learn more about NovoSeven® RT for Glanzmann’s thrombasthenia by speaking with your doctor and by visiting NovoSevenRT.com.**

Please see additional Important Safety Information, including Boxed Warning, throughout. Please click here for Prescribing Information or visit NovoSevenRT.com.

NovoSeven® RT
Coagulation Factor VIIIa (Recombinant)
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.

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.

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, sepsis (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.

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.

Use with Other Drugs

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

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.

MixPro® and NovoSeven® are registered trademarks of Novo Nordisk Health Care AG. Novo Nordisk is a registered trademark of Novo Nordisk A/S.

© 2017 Novo Nordisk All rights reserved. USA17BIO01452 June 2017