HEMOPHILIA B WITH INHIBITORS



WHEN BLEEDS HAPPEN Will you be prepared?

baseph has hemophilia B with inhibitors.





About hemophilia B with inhibitors

Hemophilia is a bleeding disorder that prevents blood from clotting properly. There are a number of proteins in blood, called clotting factors, that work together in a series of steps to form blood clots. People with hemophilia B are missing factor IX. Hemophilia B mostly affects men, but it can also affect women. Although many people inherit the condition, about one-third of people with hemophilia B do not have a family history of it.

Sometimes, the body thinks that the replacement clotting factor (FIX) used to control bleeds is foreign or harmful. In response, the body may develop antibodies, known as **inhibitors**. These inhibitors attack the clotting factor treatment and prevent it from working properly.

Bleeds happen. Treat early to reduce the damage.

It is recommended that a bleed be treated early; however, a review of registry real-world data on people with hemophilia^a showed



Delay in treatment of bleeds can cause issues such as joint inflammation, cartilage damage, and joint destruction.

^aOf 128 bleeds reported.

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



It is important to have an on-demand treatment with you to stop bleeds whenever and wherever they happen.



What is NovoSeven[®] RT?

NovoSeven[®] RT (coagulation Factor VIIa, recombinant) is an injectable medicine 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 Glanzmann's thrombasthenia with a decreased or absent response to platelet transfusions

• Treatment of bleeding and prevention of bleeding for surgeries and procedures in adults with acquired hemophilia

Please see Important Safety Information throughout. Please see <u>Prescribing Information</u>.

The one and only **NovoSeven® RT**

The Recombinant Factor VIIa (rFVIIa) TRUSTED BY PATIENTS FOR OVER 35 YEARS

FIRST

rFVIIa approved for: Hemophilia A or B with inhibitors

ONLY

rFVIIa approved for:

All ages (children, adolescents, and adults)Before, during, and after surgery

More than **1106** patients and **5305** bleeds have been treated in clinical trials and registry data.^a

^aIn clinical trials and data collected from registries, NovoSeven® RT was studied in people with hemophilia A or B with inhibitors, Glanzmann's thrombasthenia, congenital factor VII deficiency, and acquired hemophilia.





Get fast bleed control—even for the most life-threatening bleeds.^a



90%

effective

In all bleeds in hemophilia A and B with inhibitorsth A total of 227 joint, target joint, skin, and mucous membrane, muscle, and other bleeding episodes were studied.

In all severe bleeding episodes

A total of 518 severe bleeding episodes were studied. Bleeds included muscle, ENT (ear, nose, throat), CNS (central nervous system), joint and internal/retroperitoneal bleeds.



In children within a trial of patients with hemophilia A and B with and without inhibitors

20 children ages 12 and younger and 8 children ages 12 to 16 were studied. Bleeds included joint, muscle, and mucous membrane bleeds.

Important Safety Information

What is the most important information I should know about NovoSeven® RT?

NovoSeven[®] RT may cause serious side effects, including:

• 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 ^aIn compassionate use situations including surgery, central nervous system hemorrhages, severe intra-abdominal bleeding, and other life-threatening bleeding episodes.

^bProven effective in the adept[™]2 study, one of the largest clinical trials conducted in patients with hemophilia with inhibitors. The adept[™]2 study included people with hemophilia A with inhibitors (n=66) and people with hemophilia B with inhibitors (n=6). Of those who participated in the study, 57 were treated with NovoSeven[®] RT and 67 were treated with vatreptacog. ^cData shown from compassionate use program and 2 clinical studies including patients with hemophilia A or B with or without inhibitors and acquired hemophilia.



Please see additional Important Safety Information throughout.6 Please see Prescribing Information.



The one and only NovoSeven® RT

The **Only** FDA-approved recombinant factor VIIa for all ages in people with hemophilia with inhibitors.

Established safety profile that comes with experience^a

Low 0.2% rate of blood clots reported in clinical trials.^b The most common and serious side effects are blood clots.

Trust the experience of NovoSeven® RT

NovoSeven [®] RT	SevenFACT®
Over 35 years' experience controlling severe bleeds Clinical trials in people with hemophilia B with inhibitors Approved for use in all ages ^c Approved for use in surgery	3 severe bleeds were reported of 468 studied in the PERSEPT 1 trial Only 2 patients with hemophilia B with inhibitors participated in the PERSEPT 1 clinical trial Only indicated for adults and adolescents aged 12 years or older Not approved for use in surgery

^aCompassionate use, also known as expanded access, began enrolling in 1988; FDA approval received in 1999. ^bIn patients with hemophilia A or B with inhibitors.

^cIn people with acquired hemophilia, NovoSeven[®] RT is only indicated for adults.

Important Safety Information

What is the most important information I should know about NovoSeven® RT? (cont'd)

- Your healthcare provider should monitor you for blood clots during treatment with NovoSeven $^{\ensuremath{\$}}$ RT
- You should not use NovoSeven[®] RT if you have ever had allergic (hypersensitivity) reactions, including severe, whole body reactions (anaphylaxis) to NovoSeven[®] RT, any of its ingredients, or mice, hamsters, or cows. Signs of allergic reaction include shortness of breath, rash, itching (pruritus), redness of the skin (erythema), or fainting/dizziness

Please see additional Important Safety Information throughout. Please see Prescribing Information.

Effective in surgeries and procedures



NovoSeven[®] RT is approved by the FDA for treating people with hemophilia A or B with inhibitors during and after surgery and procedures.

In a clinical trial, NovoSeven[®] RT was proven to effectively control bleeds throughout the surgery process.

Percentage of patients with satisfactory bleed control:



The postoperative period: essential to surgical success

Talk with your doctor for more information about controlling bleeds during and after surgery or a procedure.





mportant Safety Information (cont'd) SPANISE What should I tell my healthcare provider before using NovoSeven® RT?

Tell your healthcare provider if you have any of the following, as these may increase your risk of blood clots:

- congenital hemophilia and are also receiving treatment with aPCCs (activated prothrombin complex concentrates)
- are an older patient particularly with acquired hemophilia and receiving other agents to stop bleeding
- history of heart or blood vessel diseases

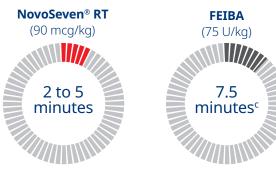
Please see additional Important Safety Information throughout. Please see <u>Prescribing Information</u>.

Experience **fast bleed control** with NovoSeven[®] RT

Fast to infuse

Faster infusion means that NovoSeven® RT gets to work stopping bleeds more quickly.

- NovoSeven[®] RT is given as an intravenous bolus injection over 2 to 5 minutes, depending on the dose administered
- NovoSeven[®] RT has **16x less infusion volume** than FEIBA^{a,b}
- NovoSeven[®] RT is up to
 3.75x faster to infuse than FEIBA^c
- Helps control bleeds in as few as
 5 hours with a median of 2 doses^d
- NovoSeven[®] RT can be redosed every 2 hours,^a which lets you dose as needed to get bleeds under control fast



• Your hemophilia treatment center and your doctor will help you decide which dosing schedule is best for you

^aIn patients with hemophilia A or B with inhibitors.

^bIndividual doses for a joint bleed are compared and based on a person weighing 88 kg (194 lb).

^cPatients are cautioned that the maximum injection or infusion rate must not exceed 10 units per kilogram of body weight per minute.

^dBased on individual dosage for joint bleeds in people with hemophilia A or B with and without inhibitors.





Less time spent dosing. More time for you.

Available in 4 different vial sizes to better meet your needs



Simple dosing delivers the results you need^a



- NovoSeven[®] RT can be redosed every 2 hours, which lets you dose as needed to get bleeds under control fast
- No daily dose restrictions

With MixPro[®], preparing a dose is as easy as



Fast to mix, fast to infuse, and fast to control bleeds

Watch the video to see how to prepare a dose with MixPro[®]

^aIn people with hemophilia A or B with inhibitors.

Important Safety Information (cont'd)

What should I tell my healthcare provider before using NovoSeven® RT? (cont'd)

• Tell your healthcare provider and pharmacist about all the medicines you take, including all prescription and non-prescription medicines, such as over-the-counter medicines, supplements, or herbal remedies

What are the possible side effects of NovoSeven[®] RT?

- 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, and seek medical help right away if you have signs of a blood clot or allergic reaction

Please see additional Important Safety Information throughout. 12 Please see Prescribing Information.



Small, compact size lets NovoSeven[®] RT go with you^b

^aPlease see Instructions for Use for complete instructions on preparing a dose. ^bNovoSeven® RT should be stored between 36 °F and 77 °F.



Trusted to stop bleeds for over 35 years^a

FIRST

ONLY

rFVIIa approved for: Hemophilia A or B with inhibitors

rFVIIa approved for:

- All ages (children, adolescents, and adults)
- Before, during, and after surgery
- 1106 patients and 5305 bleeds treated in clinical trials and registry data
- Proven control of the mildest to the most life-threatening bleeds
- Fast bleed control for all ages
- Dosing designed with you in mind
 Available in 4 vial sizes

rFVIIa=recombinant activated factor VII.

^aCompassionate use, also known as expanded access, began enrolling in 1988; FDA approval received in 1999.

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- 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
- \bullet Your healthcare provider should monitor you for blood clots during treatment with NovoSeven $^{\circledast}$ RT

Please see additional Important Safety Information throughout. Please see <u>Prescribing Information</u>.

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 US24NSVN0019

 July 2024







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