

Hemophilia with Inhibitors

IN YOUR WORLD, EXPERIENCE MATTERS



BOB has hemophilia A
with inhibitors.



Understanding hemophilia with inhibitors

Hemophilia is a bleeding disorder that prevents blood from clotting properly. People with hemophilia are missing or have less of a particular clotting factor in their bodies. As a result, they may need replacement clotting factor to help their blood clot. Patients with hemophilia A need factor VIII, and patients with hemophilia B need factor IX.

Sometimes, the body thinks that the replacement clotting factor 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.

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





Bleeds happen. Treat early to reduce the damage

People who develop inhibitors can treat prophylactically (on a regular schedule), or on-demand (after a bleed happens). Even while taking prophylactic (regular) treatment, bleeds can still happen.

It is recommended that a bleed be treated within **2 hours**; however, a review of data on people with hemophilia suggests



NEARLY 1/3 OF MILD TO MODERATE BLEEDS
ARE NOT TREATED WITHIN 2 HOURS

Delay in treatment of bleeds can cause issues such as

- Joint inflammation (pain, redness, and swelling)
- Cartilage damage (harm to the connective tissue between joints)
- Destruction of the joint (due to ongoing, long-term damage)

It's important to have an on-demand treatment with you to stop bleeds whenever they happen

NovoSeven® RT:

Experience where it matters

Controlling bleeds, whenever they happen

- Proven to treat bleeds for people with hemophilia A or B with inhibitors

Safety supported by clinical experience^a

- 0.2% rate of blood clots reported in clinical trials

Speed when it's needed

- Fast to mix, fast to infuse, and fast to control bleeds^b

NovoSeven® RT—committed to your experience

- More than 30 years of research and long-term clinical experience^c

^aFor people with hemophilia A or B with inhibitors.

^bAdminister as a slow bolus injection over 2-5 minutes, depending on the dose administered.

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

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

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
- Your healthcare provider should monitor you for blood clots during treatment with NovoSeven® RT



CHASE has hemophilia A with inhibitors.



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

NovoSeven® RT
Coagulation Factor VIIa
(Recombinant)

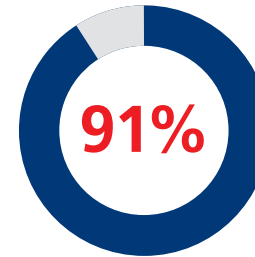




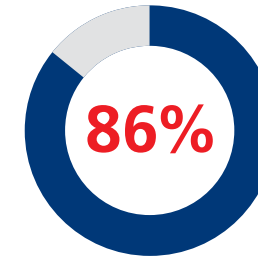
BOB has hemophilia A with inhibitors.

Experience **proven bleed control** with NovoSeven® RT

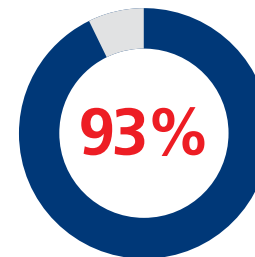
Joint bleeds



Muscle bleeds



All bleeds



- Efficacy seen in one of the largest trials studying hemophilia with inhibitors
 - Joint, target joint, skin, and mucous membrane, muscle, and other bleeding episodes (n=227 bleeding episodes)

Important Safety Information

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

NovoSeven® RT may cause serious side effects, including: (*cont'd*)

- 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



NovoSeven® RT: **Established safety** profile that comes from experience^a

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

The safety of NovoSeven® RT is well studied

- Works at the site of injury
- A low rate of blood clots (0.2%) has been reported in clinical trials^b

^bFor people 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
- Not made from human blood or plasma

NovoSeven® RT only has one main component

NovoSeven® RT	FEIBA®
Main component <ul style="list-style-type: none"> • Recombinant activated factor VII 	Main components <ul style="list-style-type: none"> • Non-activated factor II • Non-activated factor IX • Non-activated factor X • Activated factor VII

Important Safety Information

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

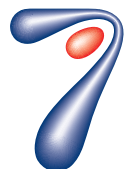


MIGUEL has hemophilia B with inhibitors.



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

NovoSeven® RT
Coagulation Factor VIIa
(Recombinant)



20
Training
session

SID has hemophilia A with inhibitors.



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

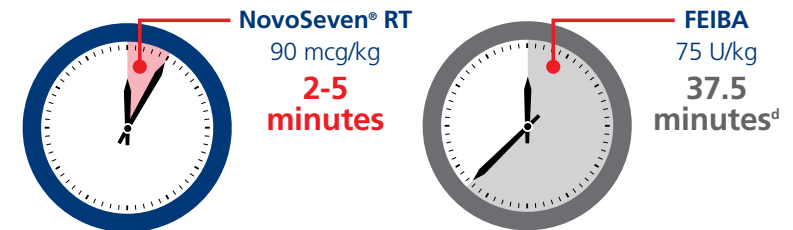
Fast to infuse

When bleeds happen, stopping them quickly is important. The faster you infuse treatment, the sooner it can start working.

- NovoSeven® RT is given as an intravenous (IV) bolus injection^a
- NovoSeven® RT has **16x less infusion volume** than FEIBA^{b,c}



- NovoSeven® RT is up to **18x faster to infuse** than FEIBA^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 (HTC) and your doctor will help you decide which dosing schedule is best for you

^aAdminister as a slow bolus injection over 2 to 5 minutes, depending on the dose administered.

^bIn patients with hemophilia A or B with inhibitors.

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

^dPatients are cautioned that the maximum injection or infusion rate must not exceed 2 units per kilogram of body weight.

Important Safety Information

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.
Please see accompanying Prescribing Information.

NovoSeven® RT
Coagulation Factor VIIa
(Recombinant)



NovoSeven® RT: Experience where it matters

Controlling bleeds, whenever they happen

- Proven to treat bleeds for people with hemophilia A or B with inhibitors

Safety supported by clinical experience^a

- 0.2% rate of blood clots reported in clinical trials

Speed when it's needed

- Fast to mix, fast to infuse, and fast to control bleeds^b

NovoSeven® RT—committed to your experience

- More than 30 years of research and long-term clinical experience^c

Learn more at NovoSevenRT.com

^aFor people with hemophilia A or B with inhibitors.

^bAdminister as a slow bolus injection over 2-5 minutes, depending on the dose administered.

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

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
- Your healthcare provider should monitor you for blood clots during treatment with NovoSeven® RT

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

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

NovoSeven® is a registered trademark of Novo Nordisk Health Care AG.
Novo Nordisk is a registered trademark of Novo Nordisk A/S.
FEIBA® is a registered trademark of Baxalta Incorporated.
© 2019 Novo Nordisk Printed in the U.S.A.
US18NSVN00084 January 2019



CHASE has hemophilia A with inhibitors.

NovoSeven® RT
Coagulation Factor VIIa
(Recombinant)

