

Bleed Have to cancel
Late for school
When will this bleed end?
Another bleed
Time Visit to ER
Frustration Bleed



For the treatment of bleeding episodes in people* with hemophilia A or B with inhibitors

I'M READY TO MOVE ON

Get rapid, predictable, and reliable bleed control with SEVENFACT 225[†]



Rapid effect: 3 hour

At 3 hours, 84% of mild/moderate bleeding episodes were controlled with a single dose



Predictable[‡] response: 84%

At 9 hours, 84% of mild/moderate bleeding episodes treated achieved bleed control after a single dose



Reliable control: 99.5%

At 24 hours, 99.5% of mild/moderate bleeding episodes were resolved



Convenient home use: 98%

98% of bleeding episodes were treated at home

[†] 225 mcg/kg initial dosing regimen in the clinical trial.

[‡] As seen in the clinical trial.

Summary of Selected Safety Information

What is the most important information I should know about SEVENFACT?

The most serious possible side effect of SEVENFACT is abnormal clotting involving blockage of blood vessels, which include stroke, blockage of the main blood vessel to the lung, and deep vein blood clots.

You should know the signs of abnormal clotting and seek medical help immediately if they occur.

Signs of clotting in places other than your site of bleeding can include new onset of swelling and pain in limbs, new onset of chest pain, shortness of breath, loss of sensation or motor power, or altered consciousness or speech.

*What is SEVENFACT?

SEVENFACT is an injectable medicine used for the treatment and control of bleeding episodes occurring in adults and adolescents 12 years of age and older with Hemophilia A or B with inhibitors.

Injecting medicines requires special training; do not attempt to self-infuse unless you have been taught how by your healthcare provider.

Who should not use SEVENFACT (coagulation factor VIIa)?

You should not use SEVENFACT if you are allergic to rabbits, or if you have known allergies to SEVENFACT or any of its components. Seek immediate medical help if you experience hives, itching, rash, difficulty breathing with cough or wheezing, swelling around the mouth and throat, tightness of the chest, dizziness or fainting, or low blood pressure after taking SEVENFACT.

Tell your healthcare provider prior to using SEVENFACT if you have begun treatment of a bleeding episode with another bypassing agent.

What should I tell my healthcare provider before I use SEVENFACT?

Tell your healthcare provider if you are pregnant, are nursing, or plan to become pregnant; if you have had prior blood clots, heart disease or heart failure, abnormal heart rhythms, prior pulmonary clots, or heart surgery; or if you have or have had any other medical conditions.

What are the possible side effects of SEVENFACT?

The most common adverse reactions for SEVENFACT are headache, dizziness, infusion-site discomfort, infusion-site hematoma, and infusion-related reaction and fever.

Seek immediate medical help if you have signs of a blood clot or an allergic reaction.

To report SUSPECTED ADVERSE REACTIONS or product complaints, contact HEMA Biologics at 1-855-718-4362. You may also report SUSPECTED ADVERSE REACTIONS to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Patient Product Information on the next page.

NEW
SevenFACT[®]
Coagulation Factor VIIa
(Recombinant)-jncw
Make the move

PATIENT PRODUCT INFORMATION

SEVENFACT® (SEV-en-fact) coagulation factor VIIa (recombinant)-jncw

For Intravenous Injection After Reconstitution Only

PLEASE READ PATIENT PRODUCT INFORMATION AND THE INSTRUCTIONS FOR USE THAT COME WITH SEVENFACT BEFORE YOU START TAKING THIS MEDICINE AND EACH TIME YOU GET A REFILL. THERE MAY BE NEW INFORMATION.

This Patient Product Information does not take the place of talking with your healthcare provider about your medical condition and treatment. If you have questions about SEVENFACT after reading this information, ask your healthcare provider.

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT SEVENFACT?

The most serious possible side effect of SEVENFACT is abnormal blood clotting involving blockage of blood vessels, which include stroke, blockage of the main blood vessel to the lung, and deep vein blood clots.

You should know the signs of abnormal clotting (thrombosis) described below and seek medical help immediately if they occur.

New onset of swelling and pain in the limbs or abdomen, new onset of chest pain, shortness of breath, loss of sensation or motor power, and altered consciousness or speech can all be signs of clot formation in places other than your site of bleeding. Seek immediate medical attention if you experience one or more of these symptoms.

SEVENFACT should be used as prescribed and directed by your healthcare provider.

WHAT IS SEVENFACT?

SEVENFACT is a recombinant human Factor VIIa protein for injection. SEVENFACT can allow adolescents and adults with Hemophilia A or B with inhibitors to create clotting at the site of bleeding without needing Coagulation Factor VIII or IX replacement.

SEVENFACT, coagulation factor VIIa (recombinant)-jncw, is indicated for the treatment and control of bleeding episodes occurring in adults and adolescents 12 years of age and older with Hemophilia A or B with inhibitors.

Injecting medications requires special training. Do not attempt to self-infuse unless you have been taught how by your health care provider or hemophilia treatment center. Once trained, you will need additional infusion materials along with your SEVENFACT so that you can successfully treat your bleeding episodes at home. Be sure to collect all necessary infusion materials before starting the reconstitution process.

SEVENFACT comes in a sterile dry powdered dosage form that must be reconstituted with sterile Water for Injection.

It is not known if SEVENFACT is safe and effective in children under 12 years of age.

WHO SHOULD NOT USE SEVENFACT?

You should not use SEVENFACT if you:

- Are allergic to rabbits.
- Have known allergies to SEVENFACT or any of its components.

Tell your doctor prior to infusing SEVENFACT if you have begun treatment of a bleeding episode with another bypassing agent such as activated prothrombin complex concentrate (FEIBA®).

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE I USE SEVENFACT?

Tell your healthcare provider if you:

- Are pregnant, planning to become pregnant or nursing, as SEVENFACT has not been studied in patients with Hemophilia A or B with inhibitors who are pregnant or nursing.
- Had prior blood clots, heart disease, heart failure, abnormal heart rhythms, prior pulmonary clots or heart surgery.
- Have or have had any other medical conditions.

You and your doctor can then decide whether SEVENFACT is the right treatment for you, as well as the proper timing and doses you will need for SEVENFACT to control your bleeding episodes at home.

HOW SHOULD I USE SEVENFACT?

Treatment with SEVENFACT should be started by a healthcare provider who is experienced in the care of patients with Hemophilia A or B with inhibitors.

SEVENFACT is given as an injection into your vein.

You may infuse SEVENFACT at a hemophilia treatment center, at your healthcare provider's office, or in your home. You should be trained on how to infuse by your healthcare provider or hemophilia treatment center. Many people with inhibitors learn to infuse by themselves or with the help of a family member.

Treating at first sign of a bleed is important for bleed management. Your healthcare provider will tell you how much

SEVENFACT to use based on your weight and when to administer SEVENFACT.

To administer SEVENFACT:

- Collect all materials needed for your prescribed dose
- Follow the **Instructions For Use** guide to reconstitute the prescribed number of SEVENFACT vials
- Infuse following your healthcare provider's instructions, using infusion materials from your pharmacy

CONTACT YOUR HEALTHCARE PROVIDER IF YOU:

- Miss a dose, or
- Administer more than your prescribed dose, or
- Think your bleed is not controlled within the expected time frame discussed with your healthcare provider.

WHAT SHOULD I AVOID WHILE USING SEVENFACT?

- Avoid activity that can create more bleeding once you have completed your SEVENFACT infusion
- Avoid mixing SEVENFACT with other medications
- Avoid infusing SEVENFACT and other factor-containing therapies [such as activated prothrombin complex concentrate (aPCC) or other recombinant Factor VIIa products] at the same time. This increases your risk of having a disabling blood clot.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF SEVENFACT?

The most common adverse reactions reported in clinical trials for SEVENFACT were headache, dizziness, infusionsite discomfort, infusionsite hematoma, infusion-related reaction and fever.

A serious allergic reaction to SEVENFACT may occur. If you experience the severe symptoms of an allergic reaction after infusing SEVENFACT, seek immediate medical attention. Severe symptoms occur when your immune system reacts very strongly to foreign proteins or drugs.

- Hives, itching, rash, difficulty breathing with cough or wheezing, swelling around the mouth and throat, tightness of the chest, dizziness or fainting, and low blood pressure are all symptoms of a severe allergic reaction (anaphylaxis). Call 911 should you experience one or more of these symptoms.

These are not all the possible side effects of SEVENFACT. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

HOW SHOULD I STORE SEVENFACT?

- SEVENFACT should be stored in its product packaging to protect from light.
- Prior to reconstitution, the SEVENFACT kit should be stored at room temperature but can be stored between 36°F to 86°F (2°C to 30°C).
- After reconstitution, SEVENFACT should be stored at room temperature but can be stored between 36°F to 86°F (2°C to 30°C), for up to 4 hours.
- SEVENFACT should not be frozen.

GENERAL INFORMATION ABOUT THE SAFE AND EFFECTIVE USE OF SEVENFACT

This leaflet summarizes the most important information about SEVENFACT.

Do not use SEVENFACT for a condition for which it was not prescribed. Do not give SEVENFACT to other people even if they have the same symptoms you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about SEVENFACT that is written for health professionals.

For more information, go to www.SEVENFACT.com or call 855.718.HEMA (4362).

WHAT ARE THE INGREDIENTS IN SEVENFACT?

Active ingredient: coagulation factor VIIa (recombinant)-jncw

INACTIVE INGREDIENTS: ARGININE HYDROCHLORIDE, GLYCINE, ISOLEUCINE, LYSINE HYDROCHLORIDE, POLYSORBATE 80, TRISODIUM CITRATE DIHYDRATE, HYDROCHLORIC ACID, NITROGEN AND WATER FOR INJECTION.

FOR INFORMATION CONTACT:

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PATENT Information: <https://hemabiodup.wpengine.com/patents/>

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