

Antihemophilic Factor (Recombinant) Recombinate



Baxter

Information for Patients Recombinate Antihemophilic Factor (Recombinant)

Pronounced: ant-eye-hee-mo-fee-lick factor

Please read this leaflet carefully before using Recombinate, Antihemophilic Factor (Recombinant) (rAHF). This leaflet is a summary of the important information you need to know about your medicine for your factor deficiency. This summary is based on the information provided to your doctor and does not contain all of the information available about Recombinate rAHF. This summary should be used only after you have received instructions from your doctor. If you have any questions after reading this leaflet, ask your doctor or pharmacist.

1. What is Recombinate rAHF?

Recombinate rAHF is a coagulation factor VIII protein that is made in a laboratory by inserting the human gene (DNA piece) that codes for Factor VIII into animal cells which then produce the human coagulation factor protein. In the manufacture of Recombinate rAHF, the human Factor VIII is purified and separated from animal cell components. Albumin, a protein purified from human plasma, is included in Recombinate rAHF to make the Factor VIII protein more stable. Factor VIII (also called antihemophilic factor), is the clotting factor that people with hemophilia A are missing. Hemophilia A is a hereditary bleeding disorder that prevents blood from clotting well. Recombinate rAHF has the same effects as factor VIII protein made from human plasma.

2. What is Recombinate rAHF used for?

Recombinate rAHF can temporarily correct your body's blood clotting process so it helps prevent and control bleeding in people with hemophilia A (classical hemophilia). But you must follow your doctor or other health care provider's instructions and schedule for infusing Recombinate rAHF carefully in order for your Recombinate rAHF treatment to work effectively. Adults and children of all ages, including newborns, may use Recombinate rAHF. Hemophilia A is a disorder that requires ongoing care. Recombinate rAHF will not work in treating other clotting disorders.

3. How does Recombinate rAHF work?

Recombinate rAHF temporarily raises the level of factor VIII in the blood to a more normal level, allowing your body's blood clotting process to function temporarily. Because of this, you must follow your doctor or other health care provider's instructions and schedule for infusing Recombinate rAHF.

4. Who should not use Recombinate rAHF?

You should not use Recombinate rAHF unless your doctor confirms that your clotting disorder is a factor VIII deficiency. Pregnant women should use this product only if clearly needed, since it is not known whether Recombinate rAHF can harm your unborn child. It is also not known if Recombinate rAHF affects a woman's ability to have children. If you are considering becoming pregnant you should talk to your doctor.

5. What is the most important information I need to know about Recombinate rAHF?

You will need to check your pulse rate before and during your administration with Recombinate rAHF. Your doctor or someone at your local hemophilia treatment center can show you how to check your pulse rate. If your pulse rate is much higher than usual you should slow the rate of infusion or temporarily stop the infusion. This should allow for your pulse to return to its normal rate. Ask your doctor how fast your pulse should be for you to slow or temporarily stop the rate of rAHF infusion.

Your body may form inhibitors to factor VIII. An inhibitor is an antibody (part of your body's normal defense system) that forms against factor VIII and prevents the factor VIII from working properly. These inhibitors can cause you to fail to respond to factor VIII therapy. This is not an uncommon complication in the treatment of people with hemophilia A. Work with your doctor to make sure you are carefully monitored for the development of inhibitors to factor VIII.

There is a possibility that you could have an allergic reaction to Recombinate rAHF. You should be aware of early signs of allergic reactions. They are: rash, hives, itching, tightness of the chest, difficulty breathing, throat tightness, weak pulse (due to low blood pressure), feeling lightheaded or feeling dizzy when you stand, and shortness of breath. If you experience any of these symptoms, stop the infusion immediately and contact your doctor. Severe symptoms, including difficulty breathing and (near) fainting require prompt emergency treatment.

6. What are the possible side effects of Recombinate rAHF?

The most common side effects are flushing, nausea, fever, chills, mild fatigue, nose bleeds, and hives.

7. How do I use Recombinate rAHF?

Recombinate, Antihemophilic Factor (Recombinant) (rAHF) is injected directly into the blood stream. When you are first starting treatment you may need or want to go to a Hemophilia Treatment Center or hospital to receive your infusions. Many people with hemophilia learn to infuse their factor by themselves or with the help of a family member. Your doctor or other health care provider can teach you the proper technique for self-infusion. Once you learn how to self-infuse, you can follow the instructions on the back of this leaflet.

8. How do I know what dose to take of Recombinate rAHF?

Your doctor will provide you with a dose that is based on your body weight, the severity of your hemophilia, and the location and severity of bleeding. Your doctor may periodically need to check laboratory blood test results following infusion of Recombinate rAHF to be sure that the blood level of active Factor VIII is high enough to allow satisfactory blood clotting. If your bleeding is not controlled after infusing Recombinate rAHF, contact your doctor.

Recombine rAHF comes in three different strengths. The boxes and bottles are color coded. The color bar on the box and bottle show you which one you have. A light blue color bar is for the low potency (220-400 IU). A light pink color bar is for the medium potency (401-800 IU). A light green color bar is for high potency (801-1240 IU). Always check the potency printed on the label to make sure you are using the potency prescribed by your doctor. Always check the expiration date printed on the bottle or box. You should not use the product after the expiration date printed on the bottle or box.

Each bottle of Recombinate rAHF is for single use only. After you add the diluent to the Recombinate rAHF it should be used within 3 hours. Any Recombinate rAHF left in the bottle at the end of your infusion should be discarded. You should not refrigerate Recombinate rAHF after you add the diluent.

9. How do I store Recombinate rAHF?

You may store Recombinate rAHF without the diluent added to it either in the refrigerator or at normal room temperature (not to exceed 86°F). DO NOT FREEZE.

10. How can I find out more about Baxter's patient assistance programs?

You can call Baxter to receive more information on patient assistance programs available to you:

- Reimbursement Support 1-800-548-4448
- Factor Assist (insurance gap program) 1-800-888-4502
- Factor Plus (indigent care program) 1-800-548-4448
- Patient Notification System 1-888-873-2838
- Baxter Customer Service 1-800-423-2090
- Hemophilia Galaxy (www.hemophiliagalaxy.com)

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Recombinate Antihemophilic Factor (Recombinant) (For intravenous use only)



1

In a quiet place, prepare a clean surface. Let the bottle with the FVIII concentrate and the Sterile Water for Injection (diluent) warm up to room temperature.



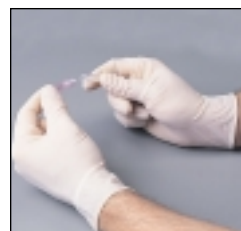
2

After washing your hands and putting on sterile gloves, remove caps from the concentrate and diluent bottles to expose the centers of the rubber stoppers.



3

Disinfect the stoppers with an alcohol swab or other suitable solution suggested by your doctor or hemophilia center.



4

Remove the protective covering from one end of the double-ended transfer needle.



5

Insert the exposed short part of the needle through the diluent stopper.



6

Remove the protective covering from the other end of the double-ended transfer needle.



7

Insert the free end of the needle through the concentrate bottle stopper at its center. The vacuum in the bottle will draw in the diluent. Invert the diluent bottle over the upright concentrate bottle.



8

Disconnect the two bottles by removing the needle from the diluent bottle stopper, then remove the needle from the concentrate bottle. Do not recap the needle! Place the needle in a hard-walled Sharps container for proper disposal.



9

Gently roll the vial between palms until all material is dissolved. **Do not shake.** Check to make sure the product is completely dissolved.



10

Attach filter needle to a disposable syringe and draw back the plunger to allow air into the syringe. Insert the needle into the reconstituted FVIII concentrate. Inject air into the bottle.



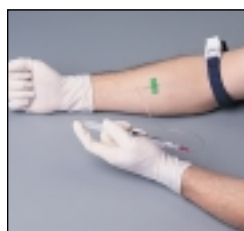
11

Withdraw the solution into the syringe.



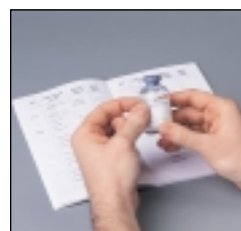
12

Prepare the injection site by wiping with an alcohol swab or other suitable solution suggested by your doctor or hemophilia center.



13

Do not infuse the product any faster than 10 mL per minute. Use a winged infusion set if available. After infusion, apply pressure with sterile gauze to the infusion site for 3 minutes. Do not recap the needle after infusion. Place it with the used syringe in a hard-walled Sharps container for proper disposal.



14

After infusion, remove peel-off label from the concentrate bottle and place it in your factor log. Clean up any spilled blood with freshly prepared 10% bleach solution or soap and water.

IMPORTANT: Contact your doctor or local Hemophilia Treatment Center if you experience any problems. These instructions are intended as a visual aid only for those patients who have been instructed by their doctor or hemophilia center on the proper way to self-infuse the product. If you have not been taught by your doctor, do not attempt to self-infuse.