

Patient Product Information
REBINYN (reh-bē-NINE)

Coagulation Factor IX (Recombinant), GlycoPEGylated

Read the Patient Product Information and the Instructions For Use that come with REBINYN 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 or treatment. If you have questions about REBINYN after reading this information, ask your healthcare provider.

What is the most important information I need to know about REBINYN?

Do not attempt to do an infusion yourself unless you have been taught how by your healthcare provider or hemophilia treatment center.

You must carefully follow your healthcare provider's instructions regarding the dose and schedule for infusing REBINYN so that your treatment will work best for you.

What is REBINYN?

REBINYN is an injectable medicine used to replace clotting Factor IX that is missing in patients with hemophilia B. Hemophilia B is an inherited bleeding disorder in all age groups that prevents blood from clotting normally.

REBINYN is used to treat and control bleeding in people with hemophilia B.

Your healthcare provider may give you REBINYN when you have surgery.

Who should not use REBINYN?

You should not use REBINYN if you

- are allergic to Factor IX or any of the other ingredients of REBINYN
- if you are allergic to hamster proteins

If you are not sure, talk to your healthcare provider before using this medicine.

Tell your healthcare provider if you are pregnant or nursing because REBINYN might not be right for you.

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

You should tell your healthcare provider if you

- Have or have had any medical conditions.
- Take any medicines, including non-prescription medicines and dietary supplements.

- Are nursing.
- Are pregnant or planning to become pregnant.
- Have been told that you have inhibitors to Factor IX.

How should I use REBINYN?

Treatment with REBINYN should be started by a healthcare provider who is experienced in the care of patients with hemophilia B.

REBINYN is given as an infusion into the vein.

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

Your healthcare provider will tell you how much REBINYN to use based on your weight, the severity of your hemophilia B, and where you are bleeding. Your dose will be calculated in international units, IU.

Call your healthcare provider right away if your bleeding does not stop after taking REBINYN.

If your bleeding is not adequately controlled, it could be due to the development of Factor IX inhibitors. This should be checked by your healthcare provider. You might need a higher dose of REBINYN or even a different product to control bleeding. Do not increase the total dose of REBINYN to control your bleeding without consulting your healthcare provider.

Use in children

REBINYN can be used in children. Your healthcare provider will decide the dose of REBINYN you will receive.

If you forget to use REBINYN

If you forget a dose, infuse the missed dose when you discover the mistake. Do not infuse a double dose to make up for a forgotten dose. Proceed with the next infusions as scheduled and continue as advised by your healthcare provider.

If you stop using REBINYN

Do not stop using REBINYN without consulting your healthcare provider.

If you have any further questions on the use of this product, ask your healthcare provider.

What if I take too much REBINYN?

Always take REBINYN exactly as your healthcare provider has told you. You should check with your healthcare provider if you are not sure. If you infuse more REBINYN than recommended, tell your healthcare provider as soon as possible.

What are the possible side effects of REBINYN?

Common Side Effects Include:

- swelling, pain, rash or redness at the location of infusion
- itching

Other Possible Side Effects:

You could have an allergic reaction to coagulation Factor IX products. **Call your healthcare provider right away or get emergency treatment right away if you get any of the following signs of an allergic reaction:** hives, chest tightness, wheezing, difficulty breathing, and/or swelling of the face.

Your body can also make antibodies called “inhibitors” against REBINYN, which may stop REBINYN from working properly. Your healthcare provider may need to test your blood for inhibitors from time to time.

You may be at an increased risk of forming blood clots in your body, especially if you have risk factors for developing blood clots. Call your healthcare provider if you have chest pain, difficulty breathing, leg tenderness or swelling.

These are not all of the possible side effects from REBINYN. Ask your healthcare provider for more information. You are encouraged to report side effects to FDA at 1-800-FDA-1088.

Tell your healthcare provider about any side effect that bothers you or that does not go away.

What are the REBINYN dosage strengths?

REBINYN comes in three different dosage strengths. The actual number of international units (IU) of Factor IX in the vial will be imprinted on the label and on the box. The three different strengths are as follows:

Cap Color Indicator	Nominal Strength
Red	500 IU per vial
Green	1000 IU per vial
Yellow	2000 IU per vial

Always check the actual dosage strength printed on the label to make sure you are using the strength prescribed by your healthcare provider.

How should I store REBINYN?

Prior to Reconstitution (mixing the dry powder in the vial with the diluent):

Store in original package in order to protect from light. Do not freeze REBINYN.

REBINYN vials can be stored in the refrigerator (36-46°F [2°C – 8°C]) for up to 24 months until the expiration date, or at room temperature (up to 86°F [30°C]) for a single period not more than 6 months.

If you choose to store REBINYN at room temperature:

- Note the date that the product is removed from refrigeration on the box.
- The total time of storage at room temperature should not be more than 6 months. Do not return the product to the refrigerator.
- Do not use after 6 months from this date or the expiration date listed on the vial, whichever is earlier.

Do not use this medicine after the expiration date which is on the outer carton and the vial. The expiration date refers to the last day of that month.

After Reconstitution:

The reconstituted (the final product once the powder is mixed with the diluent) REBINYN should appear clear without visible particles.

The reconstituted REBINYN should be used immediately.

If you cannot use the reconstituted REBINYN immediately, it should be used within 4 hours when stored at or below 86°F (30°C). Store the reconstituted product in the vial.

Keep this medicine out of the sight and out of reach of children.

What else should I know about REBINYN and hemophilia B?

Medicines are sometimes prescribed for purposes other than those listed here. Do not use REBINYN for a condition for which it is not prescribed. Do not share REBINYN with other people, even if they have the same symptoms that you have.

For more information about REBINYN, please call Novo Nordisk at 1-844-REB-INYN.

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REBINYN[®] is a trademark of Novo Nordisk A/S.

For Patent Information, refer to: <http://novonordisk-us.com/patients/products/product-patents.html>

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