

***Life doesn't have
a pause button***



RIXUBIS
[COAGULATION FACTOR
(RECOMBINANT)]

MOVING FORWARD



RIXUBIS® [Coagulation Factor IX (Recombinant)]

Important Information

What is RIXUBIS?

RIXUBIS is an injectable medicine used to replace clotting factor IX that is missing in adults and children with hemophilia B (also called congenital factor IX deficiency or Christmas disease).

RIXUBIS is used to control and prevent bleeding in people with hemophilia B. Your healthcare provider may give you RIXUBIS when you have surgery. RIXUBIS can reduce the number of bleeding episodes when used regularly (prophylaxis).

Who should not use RIXUBIS?¹

You should not use RIXUBIS if you:

- are allergic to hamsters
- are allergic to any ingredients in RIXUBIS

Tell your healthcare provider if you are pregnant or breastfeeding because RIXUBIS may not be right for you.

How often should I infuse RIXUBIS?¹

Your healthcare provider will tell you how much RIXUBIS to use based on your weight, the severity of your hemophilia B, and where you are bleeding. You may have to have blood tests done after getting RIXUBIS to be sure that your blood level of factor IX is high enough to clot your blood. Call your healthcare provider right away if your bleeding does not stop after taking RIXUBIS.

2x weekly dosing can help align factor levels with the times you are physically active.¹



Proven Efficacy¹

RIXUBIS can fit your needs with prophylactic or on-demand use.¹⁻³

Prophylactic efficacy of RIXUBIS[®] was studied in 56 previously treated patients (PTPs) between 12 and 65 years of age with severe or moderately severe hemophilia B for a mean treatment duration of 6 months.² Many patients taking RIXUBIS did not bleed over the course of the clinical study.¹ Prophylactic efficacy of RIXUBIS was studied in 23 PTPs between 1.8 and 11.8 years of age with severe or moderately severe hemophilia B for a mean treatment duration of 7.7 months.^{1,3}



43% EXPERIENCED
0 BLEEDS
WITH ROUTINE
PROPHYLACTIC TREATMENT^{1,2}



39% EXPERIENCED
0 BLEEDS
WITH ROUTINE
PROPHYLACTIC TREATMENT^{1,3}

Most bleeds were resolved with 1 to 2 infusions¹



85% of bleeds
**STOPPED WITH
1 TO 2 INFUSIONS**



89% of bleeds
**STOPPED WITH
1 TO 2 INFUSIONS**^{1,3}

What should I tell my healthcare provider before using RIXUBIS?¹

You should tell your healthcare provider if you

- have or have had any medical problems
- take any medicines, including prescription and non-prescription medicines, such as over-the-counter medicines, supplements or herbal remedies
- have any allergies, including allergies to hamsters
- are breastfeeding. It is not known if RIXUBIS passes into your milk and if it can harm your baby
- are pregnant or planning to become pregnant. It is not known if RIXUBIS may harm your unborn baby
- have been told that you have inhibitors to factor IX (because RIXUBIS may not work for you).

Please see [page 8](#) of this brochure for RIXUBIS brief summary and please see RIXUBIS full Prescribing Information.

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Safety Profile¹

In clinical trials, including 14,018 infusions of RIXUBIS[®] *

There was
NO development
of neutralizing
inhibitors to factor IX

There were
NO severe allergic
reactions

In a combined study, 99 male PTPs received a total of 14,018 infusions of RIXUBIS[®] and were treated for a median of 156 exposure days, with a median of 163 infusions.

* Low-titer, non-neutralizing antibodies against factor IX were observed in 21 (21.2%) subjects at one or more time points. No clinical adverse findings were observed in any of these 21 subjects.

What are the possible side effects of RIXUBIS?¹

Allergic reactions may occur with RIXUBIS. Call your healthcare provider or get emergency treatment right away if you get a rash or hives, itching, tightness of the throat, chest pain or tightness, difficulty breathing, lightheadedness, dizziness, nausea, or fainting.

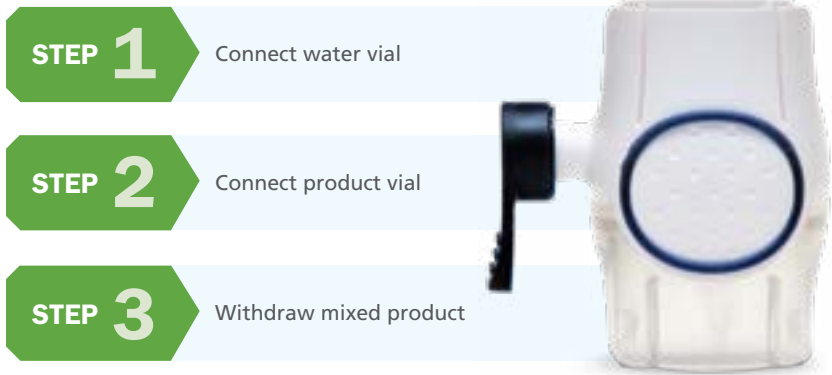
Some common side effects of RIXUBIS were unusual taste in the mouth and limb pain.

Tell your healthcare provider about any side effects that bother you or do not go away.

Your body may form inhibitors to factor IX. An inhibitor is part of the body's defense system. If you form inhibitors, it may stop RIXUBIS from working properly. Consult with your healthcare provider to make sure you are carefully monitored with blood tests for development of inhibitors to factor IX.

Injection¹

Easy mixing with the BAXJECT[®] II Needle-less Transfer device



Watch our video at RIXUBIS.com for step-by-step instructions on how to mix.

Infusing RIXUBIS with the BAXJECT II makes for a fast infusion rate with a variety of vial sizes and a wide range of dosing options.

How should I infuse RIXUBIS?¹

RIXUBIS is given directly into the bloodstream and should be administered as ordered by your healthcare provider. You should be trained on how to infuse by your healthcare provider or hemophilia treatment center. Many people with hemophilia B learn to infuse their RIXUBIS by themselves or with the help of a family member.

Your healthcare provider will tell you how much RIXUBIS to use based on your weight, the severity of your hemophilia B, and where you are bleeding. You may have to have blood tests done after getting RIXUBIS to be sure that your blood level of factor IX is high enough to clot your blood.

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We're here to support you



Visit www.RIXUBIS.com to find a wide range of support all in one place. You'll find access to unmatched resources and programs designed to make a meaningful difference in your life and your hemophilia journey.

HSC Patient Support

Takeda's Hematology Support Center (HSC) is a dedicated team here to help patients who have been prescribed Takeda hematology products with information, guidance, and resources regarding their treatment.

1-888-229-8379

Monday–Friday | 8:30AM–8:00PM EST

www.HematologySupport.com

CoPay Assistance

For eligible commercially insured Takeda patients, Takeda's CoPay assistance program covers out-of-pocket expenses related to a patient's Takeda Hematology treatment for which there is a co-pay, such as deductibles and coinsurances.

Access Support

Our Reimbursement and Access Managers can assist providers and patients with addressing barriers to treatment access by providing insurance and access education tools, including information related to prior authorizations, appeals, and billing and coding.

Educational Tools and Resources

Insurance education resources are available to help patients understand insurance and the evolving healthcare landscape. Additionally, HSC connects patients and caregivers with community resources and additional tools available for those living with a bleeding disorder. Healthcare Educators are also a part of the HSC team and are fluent in both Spanish and English.

REFERENCES:

1. RIXUBIS [Prescribing Information].
2. Windyga J, Lissitchkov T, Stasyshyn O, et al. Pharmacokinetics, efficacy and safety of BAX326, a novel recombinant factor IX: a prospective, controlled, multicentre phase I/III study in previously treated patients with severe (FIX level <1%) or moderately severe (FIX level ≤2%) haemophilia B. *Haemophilia*. 2014;20(1):15-24.
3. Urasinski T, Stasyshyn O, Andreeva T, et al. Recombinant factor IX (BAX326) in previously treated paediatric patients with haemophilia B: a prospective clinical trial. *Haemophilia*. 2015;21(2):196-203.

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Important facts about RIXUBIS®:

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This leaflet summarizes important information about RIXUBIS. Please read it carefully before using this medicine. This information does not take the place of talking with your healthcare provider.

What is RIXUBIS used for?

RIXUBIS is a medicine used to replace clotting factor (Factor IX) that is missing in people with hemophilia B. Hemophilia B is also called congenital factor IX deficiency or Christmas disease. Hemophilia B is an inherited bleeding disorder that prevents blood from clotting normally. RIXUBIS is used to prevent and control bleeding in people with hemophilia B. Your healthcare provider may give you RIXUBIS when you have surgery. RIXUBIS can reduce the number of bleeding episodes when used regularly (prophylaxis).

Who should not use RIXUBIS?

You should not use RIXUBIS if you

- are allergic to hamsters
- are allergic to any ingredients in RIXUBIS.

Tell your healthcare provider if you are pregnant or breastfeeding because RIXUBIS may not be right for you.

What should I tell my healthcare provider before using RIXUBIS?

You should tell your healthcare provider if you

- have or have had any medical problems
- take any medicines, including prescription and non-prescription medicines, such as over-the-counter medicines, supplements or herbal remedies
- have any allergies, including allergies to hamsters
- are breastfeeding. It is not known if RIXUBIS passes into your milk and if it can harm your baby
- are pregnant or planning to become pregnant. It is not known if RIXUBIS may harm your unborn baby
- have been told that you have inhibitors to factor IX (because RIXUBIS may not work for you).

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

Allergic reactions have been reported with RIXUBIS. Stop using the product and call your healthcare provider or get emergency treatment right away if you get a rash or hives; rapid swelling of the skin or mucous membranes; itching; tightness of the throat; chest pain or tightness; wheezing; difficulty breathing; low blood pressure; lightheadedness; dizziness; nausea; vomiting; tingling, prickling, burning, or numbness of the skin; restlessness; or fainting.

Your body may form inhibitors to factor IX. An inhibitor is part of the body's defense system. If you form inhibitors, it may stop RIXUBIS from working properly. Consult with your healthcare provider to make sure you are carefully monitored with blood tests for the development of inhibitors to factor IX.

The use of factor IX containing products has been associated with the development of blood clots. Talk to your doctor about your risk for potential complications and whether RIXUBIS is right for you.

What are the possible side effects of RIXUBIS?

Some common side effects of RIXUBIS were unusual taste in the mouth, limb pain, and atypical blood test results. Tell your healthcare provider about any side effects that bother you or do not go away. These are not all the side effects possible with RIXUBIS. You can ask your healthcare provider for information that is written for healthcare professionals.

What else should I know about RIXUBIS?

Consult with your healthcare provider to make sure your factor IX activity blood levels are monitored so they are right for you.

You should be trained on how to do infusions by your healthcare provider or hemophilia treatment center. Many people with hemophilia B learn to infuse their RIXUBIS by themselves or with the help of a family member.

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

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

The risk information provided here is not comprehensive. To learn more, talk about RIXUBIS with your healthcare provider or pharmacist. The FDA-approved product labeling can be found at https://www.shirecontent.com/PI/PDFs/RIXUBIS_USA_ENG.pdf or by calling 1-877-825-3327.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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Issued 05/2018
546186 02/19

