

Some images of hemophilia B patients shown are for illustrative purposes only.

### **INDICATIONS AND USAGE**

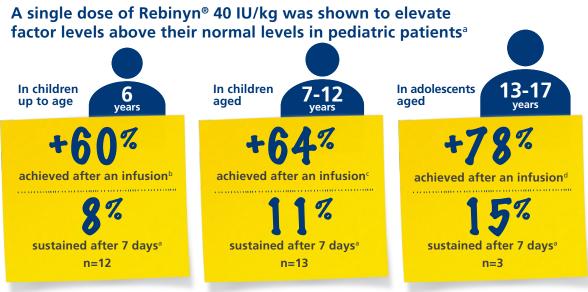
### What is Rebinyn<sup>®</sup> Coagulation Factor IX (Recombinant), GlycoPEGylated?

Rebinyn<sup>®</sup> is an injectable medicine used to replace clotting Factor IX that is missing in patients with hemophilia B. Rebinyn<sup>®</sup> is used to treat and control bleeding in people with hemophilia B. Your healthcare provider may give you Rebinyn<sup>®</sup> when you have surgery. Rebinyn<sup>®</sup> is not used for routine prophylaxis or for immune tolerance therapy.



Please see additional Important Safety Information throughout. Please see accompanying Prescribing Information. **rebinyn**° Coagulation Factor IX (Recombinant), GlycoPEGylated

## HIGH FACTOR ACTIVITY IN PEDIATRIC PATIENTS



<sup>a</sup>Based on pharmacokinetic assessment of a single dose of Rebinyn<sup>®</sup> 40 IU/kg after 7 days in 3 adolescents (mean FIX activity 14.6%), 13 children aged 7 to 12 (mean FIX activity 10.9%), and 12 children aged 0-6 (mean FIX activity 8.4%) upon enrollment in the phase 3 trials using 1-stage assay and product-specific standard. All values are geometric mean.

<sup>b</sup>Based upon a 1.51% increase in factor levels per IU/kg infused in children aged  $\leq 6$ . <sup>c</sup>Based upon a 1.59% increase in factor levels per IU/kg infused in children aged 7-12. <sup>d</sup>Based upon a 1.96% increase in factor levels per IU/kg infused in adolescents aged 13-17.

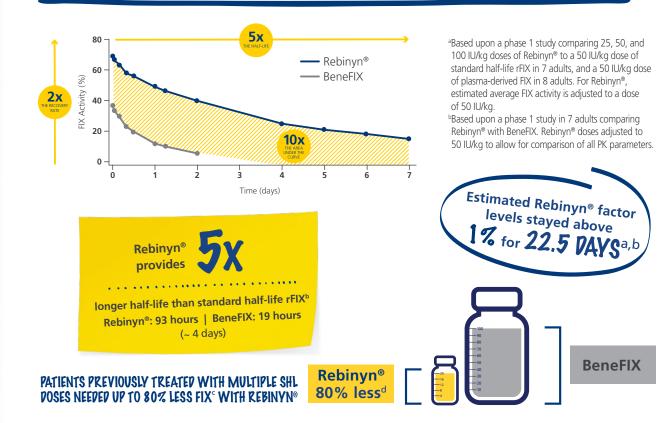


Please see additional Important Safety Information throughout. Please see accompanying Prescribing Information.



#### **IMPORTANT SAFETY INFORMATION**

## HIGHER FACTOR LEVELS FOR LONGER COMPARED TO BENEFIX®a

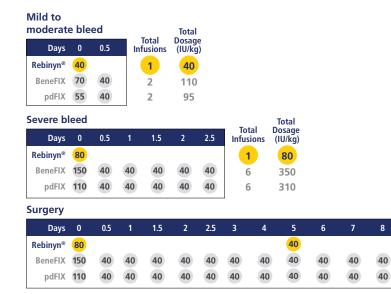


<sup>c</sup>In a phase 3 study, the efficacy of Rebinyn<sup>®</sup> in adults/adolescents was evaluated. The on-demand arm included 15 patients; 1 patient had no bleeds, the other 14 patients received Rebinyn<sup>®</sup> 40 IU/kg as single dose for the treatment of bleeds. Patients received on-demand treatment for 28 weeks. 7 patients controlled all bleeds (62 bleeds) with a single 40 IU/kg dose of Rebinyn<sup>®</sup>. The remaining 7 patients (81 bleeds) required  $\geq$ 2 doses to control at least 1 of their bleeds. Of those 7, 4 patients who were previously treated with multiple high doses (2-3 doses of 60 IU/kg or 83 IU/kg) were able to control 71% of their bleeds with a single dose and used 58%-80% less FIX while using Rebinyn<sup>®</sup> 40 IU/kg. <sup>d</sup>243 IU/kg with pdFIX vs 47.5 IU/kg with Rebinyn<sup>®</sup>. This was reported in one patient.

Please see additional Important Safety Information throughout.

#### Please see accompanying Prescribing Information.

## **REBINYN® MAY REDUCE THE NEED FOR ADDITIONAL INFUSIONS VS STANDARD HALF-LIFE BENEFIX**<sup>e-g</sup>



<sup>e</sup>A single dose should be enough for minor and moderate bleeds. Your doctor may recommend additional doses of 40 IU/kg.
<sup>f</sup>Based on population-based pharmacokinetic (PK) modeling to World Federation of Hemophilia (WFH) guidelines. Simulated results based on phase 1 PK study of Rebinyn® (n=15), BeneFIX (n=7), and plasma-derived FIX (pdFIX) (n=8).
<sup>g</sup>Compared with SHL products.

#### **IMPORTANT SAFETY INFORMATION**

#### Who should not use Rebinyn®?

Do not use Rebinyn<sup>®</sup> if you:

- are allergic to Factor IX or any of the other ingredients of Rebinyn<sup>®</sup>.
- are allergic to hamster proteins.

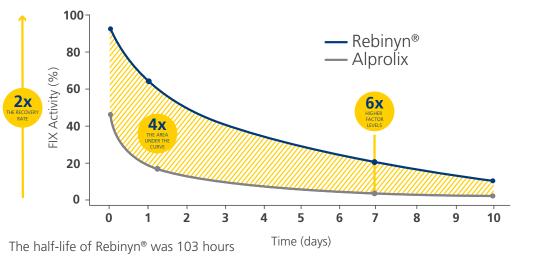
9	10	11	12	13	Total Infusions	Dosage (IU/kg)			
	40				3	160			
40	40	40	40	40	17	790			
40	40	40	40	40	17	750			

Teast

PK vs BeneFIX



## HIGHER FACTOR LEVELS FOR LONGER **COMPARED TO ALPROLIX®**a



vs 85 hours for Alprolix.

<sup>a</sup>Based upon a phase 1 trial of 15 patients who were given a single dose of Rebinyn<sup>®</sup> 50 IU/kg compared with a single dose of Alprolix 50 IU/kg using tests to measure factor activity level (1-stage and chromogenic assays). The standard Alprolix dose of 50 IU/kg was given for both products to allow for a comparison of dose-dependent measures; a dose standardized or normalized to 50 IU/kg was used to reflect minor differences in the dose given. The average (geometric mean) half-life was also prolonged (Rebinyn®: 103.2 hours, Alprolix: 84.9 hours). It was determined that the results of the measures were unlikely to be attributed to chance (significance P<0.001).

### **IMPORTANT SAFETY INFORMATION**

#### What should I tell my health care provider before using Rebinyn®?

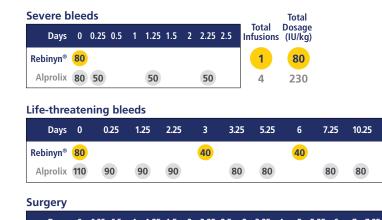
Tell your health care provider if you:

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

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

## **REBINYN® MAY REDUCE THE NEED FOR ADDITIONAL** INFUSIONS VS EXTENDED HALF-LIFE ALPROLIX<sup>b,c</sup>



Days	0	0.25	0.5	1	1.25	1.5	2	2.25 2.	53	3.25	4	5	5.25	6	7	7.25	8
Rebinyn®	80	)												40			
Alprolix	80	50			50			50		50			50			50	

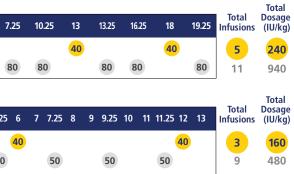
<sup>b</sup>A single dose should be enough for minor and moderate bleeds. Your doctor may recommend additional doses of 40 IU/kg. Based on PK modeling to WFH guidelines. Simulated results based on phase 1 PK studies of Rebinyn® (n=15) and Alprolix (n=15).

### **IMPORTANT SAFETY INFORMATION**

#### What should I tell my health care provider before using Rebinyn<sup>®</sup>? (cont'd)

- are nursing, pregnant, or plan to become pregnant.
- have been told you have inhibitors to Factor IX.

4x GREATER FACTOR COVERAGE 6x HIGHER at 7 days





PK vs Alprolix

## THE POWER TO CONTROL BLEEDS WHEN AND WHERE THEY HAPPEN<sup>a</sup>



bleeds treated with 1-2 infusions n=143 bleeding episodes<sup>b</sup>

rated their bleed control

defined as excellent or good

(n=142 bleeding episodes)<sup>c</sup>

as successful



Markus, 33 years old, lives with hemophilia B.

<sup>a</sup>Rebinyn<sup>®</sup> should be stored between 36°F and 86°F. <sup>b</sup>Results shown are from the on-demand arm of the adolescent/adult clinical study in previously treated patients. In this study, 15 people were treated for on-demand bleeds. In 14 people, there were a total of 143 bleeding episodes. <sup>c</sup>Results shown are based on a bleed assessment by either the patient (for home treatment) or the study investigator (for treatment under medical supervision). Bleeds were assessed using a 4-point scale of excellent, good, moderate, or poor.

#### **IMPORTANT SAFETY INFORMATION**

#### How should I use Rebinyn<sup>®</sup>?

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- Rebinyn<sup>®</sup> is given as an infusion into the vein.
- Call your healthcare provider right away if your bleeding does not stop after taking Rebinyn<sup>®</sup>.

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

## **PROTECTION IN SURGERY**

In all major surgeries and procedures studied, doctors rated Rebinyn® as excellent or good in protecting patients from bleeds<sup>d</sup>





<sup>d</sup>Results shown are from the surgery clinical study, which included 13 previously treated adolescent and adult patients. Patients received 1 infusion of Rebinyn® 80 IU/kg on the day of their surgeries. At the doctor's discretion, patients received infusions of Rebinyn® 40 IU/kg for up to 3 weeks after surgery. Across 13 surgical procedures, the success rate in bleed control during surgery was evaluated on a 4-point scale of excellent, good, moderate, or poor. Treatment success was defined as excellent or good bleed control.

## **IMPORTANT SAFETY INFORMATION**

#### How should I use Rebinyn<sup>®</sup>? (cont'd)

• Do not stop using Rebinyn<sup>®</sup> without consulting your healthcare provider.



## TAKE CONTROL OF HEMOPHILIA B WITH SIMPLE DOSING

Fixed dosing with Rebinyn<sup>®</sup> means your dose stays the same. No dosing adjustment needed—1 fixed dose for minor/moderate bleeds (40 IU/kg)<sup>a,b</sup> and 1 fixed dose for major bleeds (80 IU/kg)<sup>b</sup>



<sup>a</sup>A single dose should be enough for minor and moderate bleeds. <sup>b</sup>Your doctor may recommend additional doses of 40 IU/kg.

#### **IMPORTANT SAFETY INFORMATION**

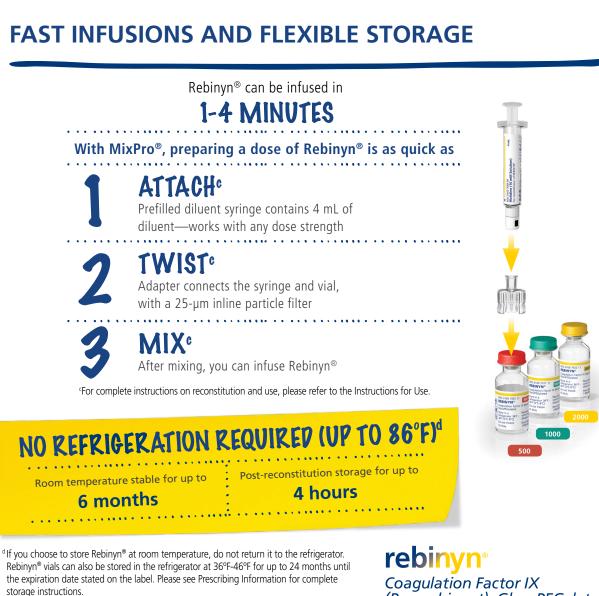
#### What are the possible side effects of Rebinyn<sup>®</sup>?

- Common side effects include swelling, pain, rash or redness at the location of the infusion, and itching.
- 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.

Please see additional Important Safety Information throughout. 10 Please see accompanying Prescribing Information.

- Follow your health care provider's instructions regarding the dose and schedule for infusing Rebinvn®
- Do not attempt to do an infusion yourself unless you have been taught how by your health care provider or hemophilia treatment center





Coagulation Factor IX (Recombinant), GlycoPEGylated 11

**Dosing and Usage** 

## **DESIGNED FOR SAFETY**

### Rebinyn<sup>®</sup> was shown to be safe and effective



- Side effects included allergic reaction to medication (1%), itching (3%), and injection site reactions  $(4\%)^{a}$
- Your body may make antibodies called inhibitors against Factor IX (Rebinyn<sup>®</sup>), which may stop Rebinyn<sup>®</sup> from working properly. Your doctor may test your blood for inhibitors
- You may be at an increased risk of forming blood clots

aln previously treated patients with moderate to severe hemophilia (<2% factor levels), including 40 treated for 2 or more years.

### **IMPORTANT SAFETY INFORMATION**

#### What are the possible side effects of Rebinyn<sup>®</sup>? (cont'd)

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

Please see additional Important Safety Information throughout. 12 Please see accompanying Prescribing Information.



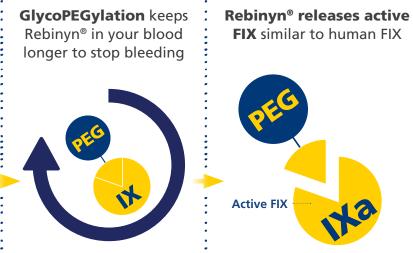
lives with hemophilia B and uses Rebinyn®, and his sister, Gense

## **REBINYN® WORKS IN YOUR BODY** LONGER TO CONTROL BLEEDS

### PEGylation<sup>b</sup> is a technology used to extend half-life

The PEG molecule is designed to attach to a specific part of Rebinyn®





<sup>b</sup>PEG=polyethylene glycol.

### **IMPORTANT SAFETY INFORMATION**

#### What are the possible side effects of Rebinyn<sup>®</sup>? (cont'd)

• Animals given repeat doses of Rebinyn<sup>®</sup> showed Polyethylene Glycol (PEG) inside cells lining blood vessels in the choroid plexus, which makes the fluid that cushions the brain. The potential human implications of these animal tests are unknown.



Safety and Technology



<sup>a</sup>Patients who have been prescribed a Novo Nordisk hemophilia and rare bleeding disorder product for an FDA-approved indication, and who have commercial insurance, may be eligible to receive a limited supply of free product. Patients who participate in any government, state, or federally funded medical or prescription benefit programs, including Medicare, Medicaid, Medigap, VA, DOD, and TRICARE, including patients who participate in a managed Medicaid program or have Medicaid as secondary insurance, are not eligible to receive product support. Product is provided at no cost to the patient or the HCP, is not contingent on any product purchase, and the patient and HCP must not: (1) bill any third party for the free product, or (2) resell the free product.

<sup>b</sup>The Novo Nordisk Patient Assistance Program (PAP) is administered by NovoSecure<sup>™</sup>. To qualify for the PAP, patients must demonstrate financial need and must have attempted to find alternative reimbursement. Several factors are considered in evaluating financial need, including cost of living, size of household, and burden of total medical expenses. If the applicant gualifies under the PAP guidelines,

a limited supply of the requested medication(s) will be shipped to the patient. Patients who qualify for PAP may be eligible to receive the prescribed Novo Nordisk product, for up to 1 year from the approval date. Product limits vary.

Novo Nordisk Hemophilia and Rare Bleeding Disorders Co-Pay/Coinsurance Terms and Conditions: Enrolled patients are eligible for up to \$12,000 in co-pay/coinsurance assistance per calendar year for each NNI hemophilia or rare bleeding disorder product. Assistance is retroactive to 60 days. Patients must be commercially insured and may not be participating in any government, state, or federally funded medical or prescription benefit programs, including Medicare, Medicaid, Medigap, VA, DOD, and TRICARE, including patients who participate in a managed Medicaid program or have Medicaid as secondary insurance. Uninsured, cash-paying patients are not eligible to participate. Patients are eligible to receive co-pay/ coinsurance assistance on an annual basis (12 months). Offer good only in the USA, Puerto Rico, Guam, Saipan, and Virgin Islands with participating pharmacies and cannot be redeemed at government-subsidized clinics. Void where taxed, restricted, or prohibited by law. Absent a change in Massachusetts law, effective July 1, 2019, the Savings Card will no longer be valid for residents of Massachusetts. Patient is responsible for complying with any insurance carrier co-payment disclosure requirements, including disclosing any savings received from this program. Re-confirmation of information may be requested periodically to ensure accuracy of data and compliance with terms. This is not an insurance program. Novo Nordisk reserves the right to rescind, revoke, or amend this offer without notice at any time. Nonmedication expenses, such as ancillary supplies or administration-related costs, are not eligible. Must have a current prescription for an FDA-approved indication.

Please see additional Important Safety Information throughout. 14 Please see accompanying Prescribing Information.

## **STAY ON THE GO**

Small travel case holds your factor so it's ready when you are



#### INDICATIONS AND USAGE

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Rebinyn<sup>®</sup> is an injectable medicine used to replace clotting Factor IX that is missing in patients with hemophilia B. Rebinyn<sup>®</sup> is used to treat and control bleeding in people with hemophilia B. Your healthcare provider may give you Rebinyn<sup>®</sup> when you have surgery. Rebinyn<sup>®</sup> is not used for routine prophylaxis or for immune tolerance therapy.





REBINYN®

s with hemophilia B and uses Rel

# TAKE CONTROL TO A HIGH LEVEL

## **REBINYN® ACHIEVES HIGHER FACTOR LEVELS FOR LONGER**



<sup>a</sup>Based upon a phase 1 study comparing 25, 50, and 100 IU/kg doses of Rebinyn<sup>®</sup> to a 50 IU/kg dose of standard half-life rFIX in 7 adults and a 50 IU/kg dose of plasma-derived FIX in 8 adults. For Rebinyn<sup>®</sup>, estimated average FIX activity is adjusted to a dose of 50 IU/kg.

<sup>b</sup>Based upon a phase 1 study comparing a single 50 IU/kg dose of Rebinyn<sup>®</sup> to a single 50 IU/kg dose of extended half-life rFIXFc in 15 adults. For Rebinyn<sup>®</sup>, estimated average FIX activity is adjusted to a dose of 50 IU/kg.

- Rebinyn<sup>®</sup> is not used for routine prophylaxis or for immune tolerance therapy.
- Animals given repeat doses of Rebinyn<sup>®</sup> showed Polyethylene Glycol (PEG) inside cells lining blood vessels in the choroid plexus, which makes the fluid that cushions the brain. The potential human implications of these animal tests are unknown.

### **IMPORTANT SAFETY INFORMATION**

#### 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. Carefully follow your healthcare provider's instructions regarding the dose and schedule for infusing Rebinyn<sup>®</sup>.

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.



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## rebinyn®

Coagulation Factor IX (Recombinant), GlycoPEGylated