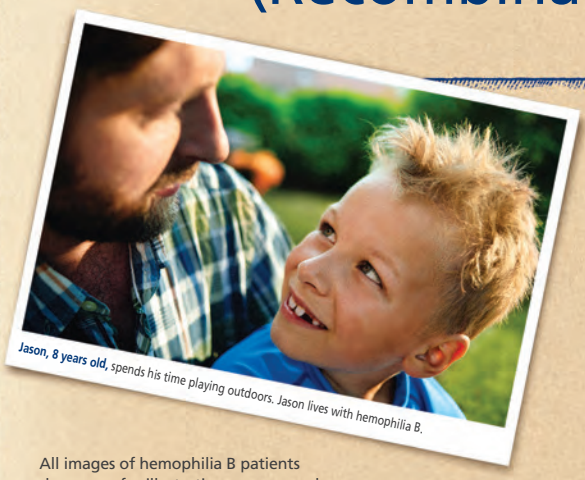
Markus, 33 years old, enjoys playing pool and spending time with his family. Markus lives with hemophilia B.

WHY REBINYN®

Coagulation Factor IX (Recombinant), GlycoPEGylated



Jason, 8 years old, spends his time playing outdoors. Jason lives with hemophilia B.

Rebinyn®—Reach for high factor levels in hemophilia B[1]

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

INDICATIONS AND USAGE

Rebinyn®, Coagulation Factor IX (Recombinant), GlycoPEGylated, is a recombinant DNA derived coagulation Factor IX concentrate indicated for use in adults and children with hemophilia B for on demand treatment and control of bleeding episodes and perioperative management of bleeding.

Limitations of Use: Rebinyn® is not indicated for routine prophylaxis or for immune tolerance induction in patients with hemophilia B.

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

novo nordisk®

rebinyn®
Coagulation Factor IX (Recombinant), GlycoPEGylated

TAKE CONTROL WITH HIGH FACTOR ACTIVITY

In a phase 3 study of adults with ≤2% factor levels, a single dose of Rebinyn® 40 IU/kg was shown to

Elevate factor levels above baseline levels[1,a]

+94%
achieved after an infusion[1,b]

17%
sustained after 7 days[1,a]
n=6

[a]Based on pharmacokinetic (PK) assessment of a single dose of Rebinyn® 40 IU/kg in 6 adults (mean FIX activity 16.8%), 3 adolescents (mean FIX activity 14.6%), 13 children aged 7-12 (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.

[b]Based upon a 2.34% increase in factor levels per IU/kg infused in adults.

Rebinyn® achieved an 83-hour mean half-life in adults[1,a]

IMPORTANT SAFETY INFORMATION

Contraindications

- Rebinyn® is contraindicated in patients with a known hypersensitivity to Rebinyn® or its components, including hamster proteins.

Warnings and Precautions

- Hypersensitivity reactions, including anaphylaxis, may occur. Signs may include angioedema, chest tightness, difficulty breathing, wheezing, urticaria, and itching. Discontinue Rebinyn® if allergic or anaphylactic-type reactions occur and initiate appropriate treatment.

Please see additional Important Safety Information throughout.
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HIGH FACTOR ACTIVITY IN PEDIATRIC PATIENTS

In paradigm™ 2 and paradigm™ 5, a single dose of Rebinyn® 40 IU/kg was shown to elevate factor levels above baseline in pediatric patients[1,c]

In children aged ≤6 years	In children aged 7-12 years	In adolescents aged 13-17 years
+60% achieved after an infusion[1,d]	**+64%** achieved after an infusion[1,e]	**+78%** achieved after an infusion[1,f]
8% sustained after 7 days[1,c] n=12	**11%** sustained after 7 days[1,c] n=13	**15%** sustained after 7 days[1,c] n=3

[c]Based on PK assessment of a single dose of Rebinyn® 40 IU/kg in 3 adolescents (mean FIX activity 14.6%), 13 children aged 7-12 (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.[1]

[d]Based upon a 1.51% increase in factor levels per IU/kg infused in children aged ≤6.[1]

[e]Based upon a 1.59% increase in factor levels per IU/kg infused in children aged 7-12.[1]

[f]Based upon a 1.96% increase in factor levels per IU/kg infused in adolescents aged 13-17.[1]

Emili, whose son, **Xander,** lives with hemophilia B and takes Rebinyn®.

rebinyn®
Coagulation Factor IX (Recombinant), GlycoPEGylated

ACHIEVE HIGHER FACTOR ACTIVITY FOR LONGER COMPARED WITH BENEFIX®

In a phase 1 study, compared to BeneFIX, Rebinyn® was shown to[2,a]

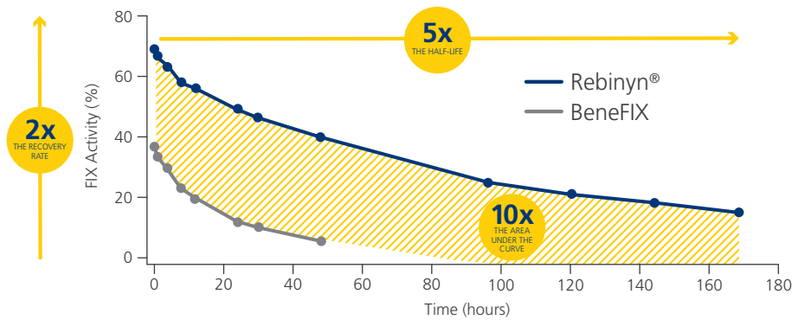
Increase FIX activity	Prolong time in the body	Keep FIX activity higher
2x	**5x**	**10x**
Recovery rate[2,a]	Half-life[2,a]	Area under the curve[2,a]
• **Rebinyn®: 1.31%[b]**	• **Rebinyn®: 93 hours**	• **Rebinyn®: 72[c]**
• BeneFIX: 0.68%[b]	• BeneFIX: 19 hours	• BeneFIX: 7[c]

[b]Per IU/kg.

[c](U x h/mL).

- Rebinyn® is not approved for routine prophylaxis.
- Animals given repeat doses of Rebinyn® showed accumulation of PEG in the choroid plexus. The potential clinical implications of these animal findings are unknown.

Rebinyn® achieved and maintained higher factor activity[2,a]



In this study, the estimated time to 1% with Rebinyn® was 22.5 days[2,c]

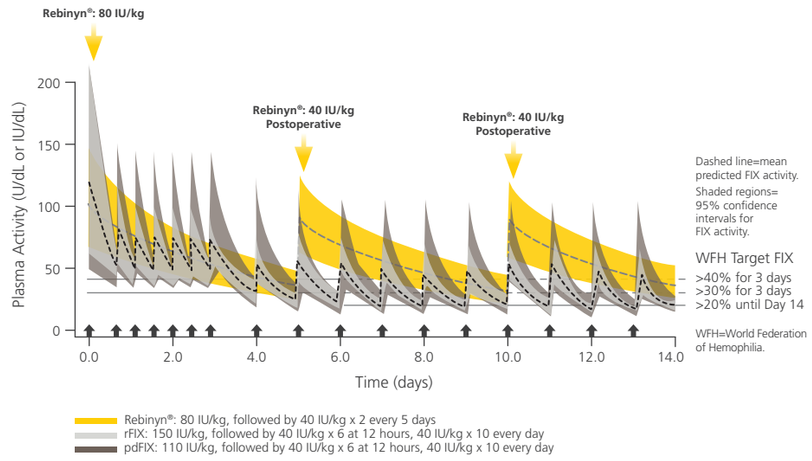
[a]Based upon a phase 1 study of patients administered 1 of 3 doses of Rebinyn® (25, 50, or 100 IU/kg) compared with one 50 IU/kg dose of their prior SHL recombinant FIX (rFIX) (n=7) or plasma-derived FIX (pdFIX) (n=8) using a 1-stage assay and product-specific standard. For Rebinyn®, estimated mean activity is adjusted to a dose of 50 IU/kg. Differences were similar in comparison of Rebinyn® to pdFIX (recovery 1.3 vs 1.1 IU/dL per IU/kg, 1.2x; half-life 93 vs 18 hours, 5.2x; area under the curve [AUC] 70 vs 9 U x h/mL, 8x).[2]

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

AN INITIAL DOSE OF REBINYN® WAS PREDICTED TO MAINTAIN FIX LEVELS IN SURGERY

A single 80 IU/kg dose of Rebinyn®, followed by two 40 IU/kg doses, was predicted to maintain target FIX levels for a 2-week postoperative period using PK simulations[3]

Rebinyn® achieved and maintained higher factor activity[3]



3 doses of Rebinyn®
vs 17 doses of BeneFIX or pdFIX were required to maintain the same WFH target FIX activity level[3]

Scan here to view additional modeling data

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

- Development of neutralizing antibodies (inhibitors) to Factor IX may occur. Monitor patients for development of factor IX inhibitors if bleeding is not controlled with the recommended dose of Rebinyn® or if expected Factor IX activity plasma levels are not attained. Factor IX activity assay results may vary with the type of activated partial thromboplastin time reagent used.

rebinyn®
Coagulation Factor IX (Recombinant), GlycoPEGylated

HIGHER FACTOR ACTIVITY SUSTAINED OVER 7 DAYS COMPARED WITH ALPROLIX

In a phase 1 study, Rebinyn® was shown to[4,a]

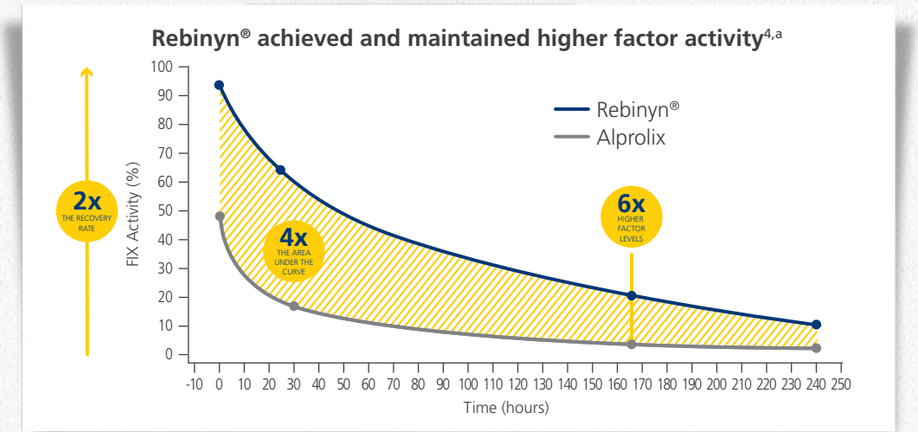
Keep FIX activity higher	Increase FIX activity	Maintain FIX levels at 7 days
4x	**2x**	**6x**
Area under the curve[4,a]	Recovery rate[4,a]	Higher factor levels[4,a]
• **Rebinyn®: 96.6**[b]	• **Rebinyn®: 1.7%**[c]	• **Rebinyn®: 19%**
• Alprolix: 22.0[b]	• Alprolix: 0.8%[c]	• Alprolix: 3%
P<0.001	*P*<0.001	*P*<0.001

[a]Based upon a phase 1 study of 15 patients administered a single dose of Rebinyn® 50 IU/kg compared with a single dose of Alprolix 50 IU/kg using both 1-stage (shown above) and chromogenic assays. The standard Alprolix dose of 50 IU/kg was administered for both products to allow for comparison of dose-dependent parameters; dose normalized to 50 IU/kg to reflect minor differences in dose administered. Geometric mean half-life was also prolonged (Rebinyn: 103.2 hours, Alprolix: 84.9 hours). All comparisons were significant (*P*<0.001) for both assays.[4]

[b]IU x h/mL.

[c]Per IU/kg.

Comparison of Rebinyn® and Alprolix



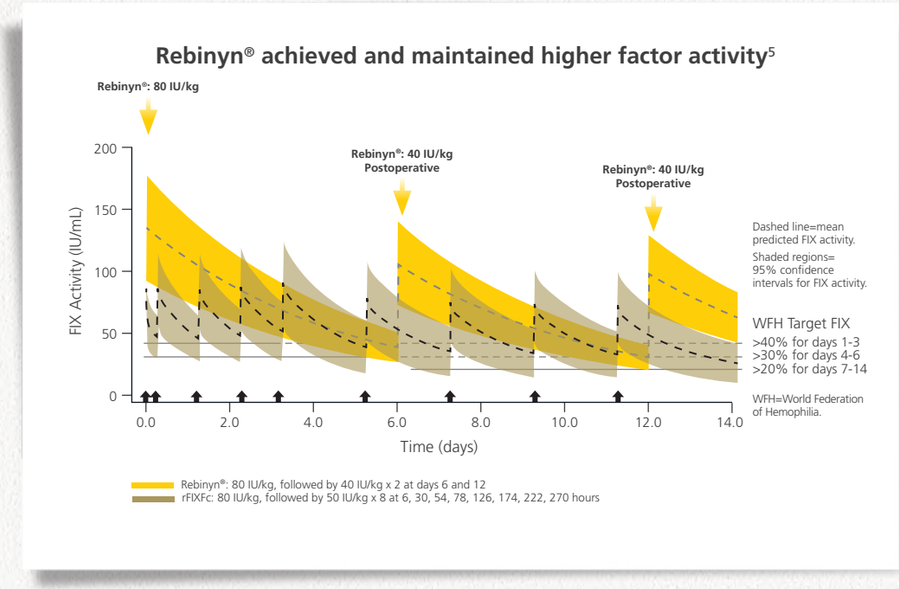
- The clinical relevance of these PK differences is unknown
- Rebinyn® is not approved for routine prophylaxis

The half-life of Rebinyn® was 103 hours vs 85 hours for Alprolix.[4]

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

AN INITIAL DOSE OF REBINYN® WAS PREDICTED TO MAINTAIN FIX LEVELS IN MAJOR SURGERY

A single 80 IU/kg dose of Rebinyn®, followed by two 40 IU/kg doses, was predicted to maintain target FIX levels for a 2-week postoperative period using PK simulations[5]



3 doses of Rebinyn®
vs 9 doses of Alprolix were required to maintain the same WFH target FIX activity level[5]

Scan here to view additional modeling data

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

- The use of Factor IX-containing products has been associated with thrombotic complications. Monitor for thrombotic and consumptive coagulopathy when administering Rebinyn® to patients with liver disease, post-operatively, to newborn infants, or to patients at risk of thrombosis or disseminated intravascular coagulation (DIC).
- Nephrotic syndrome has been reported following immune tolerance induction therapy with Factor IX products in hemophilia B patients with Factor IX inhibitors, often with a history of allergic reactions to factor IX. The safety and efficacy of using Rebinyn® for immune tolerance induction have not been established.

rebinyn®
Coagulation Factor IX (Recombinant), GlycoPEGylated

REBINYN® MAY REDUCE THE NEED FOR ADDITIONAL INFUSIONS[a-c]

Estimated number of doses and amount of FIX per episode[3,5]

Mild to moderate bleed

Days	0	0.5	Total Infusions	Total Dosage (IU/kg)
Rebinyn®	40		1	40
rFIX	70	40	2	110
pdFIX	55	40	2	95

Severe bleed

Days	0	0.25	0.5	1	1.25	1.5	2	2.25	2.5	Total Infusions	Total Dosage (IU/kg)
Rebinyn®	80									1	80
rFIX	150		40	40		40	40		40	6	350
pdFIX	110		40	40		40	40		40	6	310
rFIXFc	80	50			50			50		4	230

Life-threatening bleeds

Days	0	0.25	1.25	2.25	3	3.25	5.25	6	7.25	10.25	13	13.25	16.25	18	19.25	Total Infusions	Total Dosage (IU/kg)
Rebinyn®	80				40			40			40			40		5	240
rFIXFc	110	90	90	90		80	80		80	80		80	80		80	11	940

Surgery

Days	0	0.25	0.5	1	1.25	1.5	2	2.25	2.5	3	3.25	4	5	5.25	6	7	7.25	8	9	9.25	10	11	11.25	12	13	Total Infusions	Total Dosage (IU/kg)
Rebinyn®	80												40								40					3	160
rFIX	150		40	40		40	40		40	40		40	40		40	40		40	40		40	40		40	40	17	790
pdFIX	110		40	40		40	40		40	40		40	40		40	40		40	40		40	40		40	40	17	750
Rebinyn®	80														40									40		3	160
rFIXFc	80	50			50			50			50			50			50			50			50			9	480

Intracranial hemorrhage

Days	0	0.5	1	1.5	2	2.5	3	3.5	4	4.5	5	5.5	6	6.5	7	8	9	10	11	12	13	14	15	16	17	18	19	20	Total Infusions	Total Dosage (IU/kg)
Rebinyn®	80				40						40									40					40				5	240
rFIX	140	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	28	1490
pdFIX	100	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	28	1450

[a]A single dose should be enough for minor and moderate bleeds. Your doctor may recommend additional doses of 40 IU/kg.[3]

[b]Based on a PK modeling to WFH guidelines. Simulated results based on phase 1 PK studies of Rebinyn® (n=30), rFIX (n=7), pdFIX (n=8), and rFIXFc (n=15).[3]

[c]Based on a PK modeling to WFH guidelines. Simulated results based on a phase 1 PK study of Rebinyn (n=15).[5]

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse Reactions

- The most common adverse reactions reported in clinical trials (≥1%) were itching and injection site reactions.

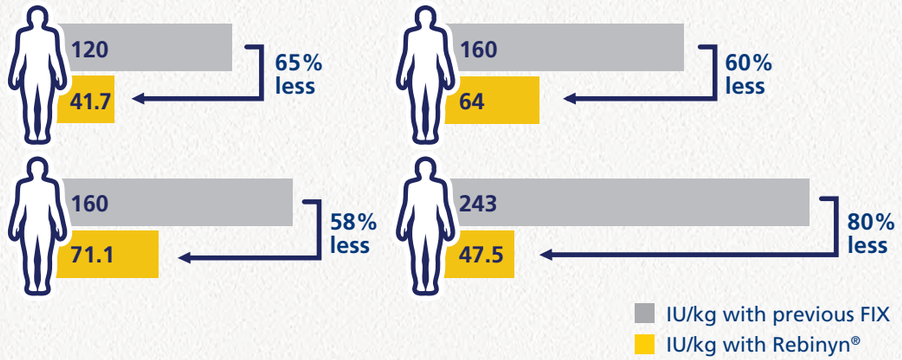
Please see additional Important Safety Information throughout.
Please see accompanying Prescribing Information.

REBINYN® REDUCES THE AMOUNT OF FIX NEEDED

In a phase 3 study in previously treated adolescents and adults[6]

- Half of the patients treated on-demand were able to resolve all bleeds with a single dose of Rebinyn®
- Of the remaining patients, those previously treated with multiple high doses[d] saw a significant decrease in FIX use with Rebinyn®

Patients previously treated with multiple SHL doses needed up to 80% less FIX[d] with Rebinyn®[6]



[d]In a phase 3 study, the efficacy of Rebinyn® in adults/adolescents was evaluated. The on-demand arm included 15 patients; 1 patient had no bleeds; the other 14 patients received Rebinyn® 40 IU/kg for the treatment of bleeds. Patients received on-demand treatment for 28 weeks. Seven patients controlled all bleeds (62 bleeds) with a single 40 IU/kg dose of Rebinyn®. The remaining 7 patients (81 bleeds) required ≥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® 40 IU/kg.[6]

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse Reactions (cont'd)

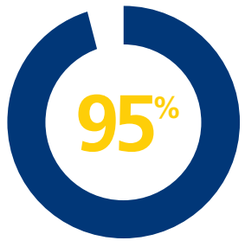
- Animals administered repeat doses of Rebinyn® showed accumulation of PEG in the choroid plexus. The potential clinical implications of these animal findings are unknown.

rebinyn®
Coagulation Factor IX (Recombinant), GlycoPEGylated

PK-Reduced Infusions

ACHIEVE CONTROL WHEN BLEEDS OCCUR

bleeds treated with 1-2 infusions[1]
n=143 bleeding episodes[a]



rated their bleed control as successful (defined as excellent or good)[1,b]
n=142 bleeding episodes

rated their bleed control as successful (defined as excellent or good)[7]
n=42 bleeding episodes

[a]Results shown are from the on-demand arm of the adolescent/adult trial, in which 15 previously treated adolescent/adult subjects were treated for on-demand bleeds. In 14 subjects, there were a total of 143 bleeding episodes. In 1 subject, no bleeding episode data were recorded.[1]

[b]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.[1]

Abdiel, lives with hemophilia B and takes Rebinyn®.

IMPORTANT SAFETY INFORMATION (cont'd)

Contraindications

- Rebinyn® is contraindicated in patients with a known hypersensitivity to Rebinyn® or its components, including hamster proteins.

Warnings and Precautions

Hypersensitivity reactions, including anaphylaxis, may occur. Signs may include angioedema, chest tightness, diffi culty breathing, wheezing, urticaria, and itching. Discontinue Rebinyn® if allergic or anaphylactic-type reactions occur and initiate appropriate treatment.

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

PROTECTION FROM A SINGLE DOSE DURING SURGERY

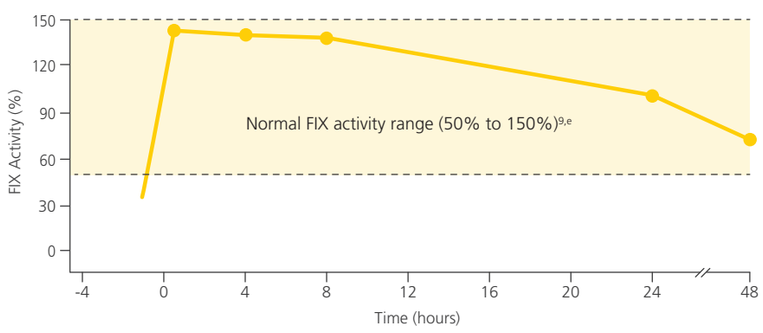
In all major surgeries studied[1,c]

Single 80 IU/kg
preoperative dose[1]

100%
intraoperative success rate[1]

[c]Results shown are from the surgery trial, which included 13 previously treated adolescent and adult subjects. On the day of their respective surgeries, patients received 1 infusion of Rebinyn® 80 IU/kg. Postoperatively, subjects received infusions of Rebinyn® 40 IU/kg at the investigator's discretion for up to 3 weeks after surgery. Across 13 surgical procedures (9 major)—which included 9 orthopedic, 1 gastrointestinal, and 3 oral cavity procedures—the hemostatic effect during surgery was evaluated on a 4-point scale of excellent, good, moderate, or poor. Treatment success was defined as excellent or good hemostasis.[1]

FIX activity sustained up to 48 hours postsurgery[1,8,d]



[d]In the surgery study, mean FIX activity following an initial preoperative Rebinyn® 80 IU/kg in 13 procedures was assessed by 1-stage assay with product-specific standard. At 8 and 24 hours, 1 subject who had no FIX activity measurement obtained was excluded. At 48 hours, 2 subjects who had no FIX activity measurement obtained were excluded and 4 subjects re-dosed prior to the second day after surgery for whom FIX activity at 24 hours were 84%, 112%, 131%, and 134%. The FIX activity at 48 hours reflects a measurement on the second day after surgery (range 47-57 hours).[1]

[e]Range shaded represents the normal population FIX activity range of 50% to 150%.[9]

rebinyn®
Coagulation Factor IX (Recombinant), GlycoPEGylated

DESIGNED FOR SAFETY

In clinical trials, 115 previously treated male patients were given Rebinyn® for 8801 exposure days[1]

0

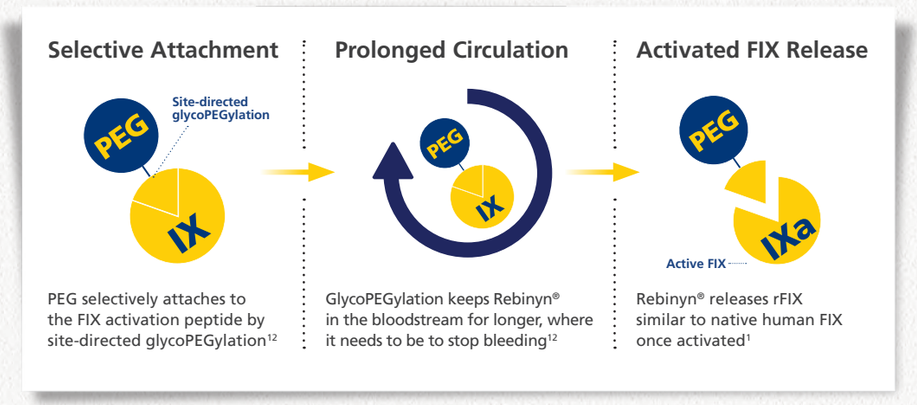
Inhibitors and thrombotic events[1,7,10,a]

Adverse reactions include hypersensitivity (1%), itching (3%), and injection-site reactions (4%)[1,a]

Formation of inhibitors and thrombotic complications have been associated with FIX treatment. Monitor patients for the development of inhibitors and signs of thrombosis[1]

[a]Identified in 115 previously treated patients who were treated with Rebinyn® in clinical studies. A previously treated patient was defined as a subject with a history of at least 150 exposure days to other FIX products (adolescent/adult subjects) or 50 exposure days to other FIX products (pediatric subjects) and no history of inhibitors. There were a total of 8801 exposure days, equivalent to 170 patient-years. A total of 40 patients (35%) were treated for more than 2 years.[1]

PEGylation[b] is a technology used to extend half-life[11]



[b]PEG=polyethylene glycol.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions

Adverse Reactions

- The most common adverse reactions reported in clinical trials (≥1%) were itching and injection site reactions.
- Animals administered repeat doses of Rebinyn® showed accumulation of PEG in the choroid plexus. The potential clinical implications of these animal findings are unknown.

Please see additional Important Safety Information throughout.
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TAKE CONTROL WITH SIMPLIFIED DOSING

Unlike other FIX products, there is no need to calculate desired FIX activity levels when determining the appropriate dose[1,13-17]

The recommended dose for all patients is

40 IU/kg

for minor or moderate bleeds[1,c]

- 80 IU/kg for major bleeds[c]

[c]A single dose should be sufficient for minor and moderate bleeds. Additional doses of 40 IU/kg can be given.[1]

Rebinyn® can be infused in 1-4 minutes[1]

With MixPro®, preparing a dose of Rebinyn® is as quick as

ATTACH[1,d]

Prefilled diluent syringe contains 4 mL of diluent—works with any dose strength

TWIST[1,d]

Adapter connects the syringe and vial, with a 25-µm inline particle filter

MIX[1,d]

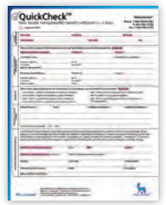
After mixing the reconstituted solution can be administered

[d]For complete instructions on reconstitution and administration, please refer to the Instructions for Use.[1]

rebinyn®
Coagulation Factor IX (Recombinant), GlycoPEGylated

RESOURCES FOR YOU AND YOUR PATIENTS

Scan each code below using the camera on your smartphone for more information

Reconstitution Video	Trial Program	Patient Assistance Programs	HCP Assistance and Support
			

References: 1. Rebinyn [package insert]. Plainsboro, NJ: Novo Nordisk Inc; May 2017. **2.** Negrier C, Knobe K, Tiede A, Giangrande P, Møss J. Enhanced pharmacokinetic properties of a glycoPEGylated recombinant factor IX: a first human dose trial in patients with hemophilia B. *Blood*. 2011;118(10):2695-2701. **3.** Collins PW, Møss J, Knobe K, et al. Population pharmacokinetic modeling for dose setting of nonacog beta pegol (N9-GP), a glycoPEGylated recombinant factor IX. *J Thromb Haemost*. 2012;10(11):2305-2312. **4.** Ettingshausen C, Hegemann I, Simpson M, et al. Favorable pharmacokinetics in hemophilia B for nonacog beta pegol versus recombinant factor IX-Fc fusion protein: a randomized trial. *Res Pract Thromb Haemost*. 2019;3(2):268-276. **5.** Simpson M, Kulkarni R, Ettingshausen C, et al. Population pharmacokinetic modeling of on-demand and surgical use of nonacog beta pegol (N9-GP) and rFIXFc based upon the paradigm 7 comparative pharmacokinetic study. *J Blood Med*. 2019;10:391–398. **6.** Escobar M, Walsh C, Cooper D, Young G. Efficacy of on-demand treatment of bleeding episodes in hemophilia B patients with extended half-life N9-GP in pivotal trials: an in-depth analysis of treatment. Poster presented at: 70th NHF Bleeding Disorders Conference; October 11-13, 2018; Orlando, FL. **7.** Carcao M, Zak M, Abdul Karim F, et al. Nonacog beta pegol in previously treated children with hemophilia B: results from an international open-label phase 3 trial. *J Thromb Haemost*. 2016;14(8):1521-1529. **8**. Escobar MA, Tehranchi R, Karim FA, et al. Low-factor consumption for major surgery in haemophilia B with long-acting recombinant glycoPEGylated factor IX. *Haemophilia*. 2017;23(1):67-76. **9.** 1-Stage APTT-Based Factor Assays. Practical-Haemostasis website. http://practical-haemostasis.com/Factor%20Assays/1_stage_aptt_assays.html. Accessed October 27, 2019. **10.** Collins PW, Young G, Knobe K, et al. Recombinant long-acting glycoPEGylated factor IX in hemophilia B: a multinational randomized phase 3 trial. *Blood*. 2014;124(26):3880-3886. **11.** Swierczewska M, Lee KC, Lee S. What is the future of PEGylated therapies? *Expert Opin Emerg Drugs*. 2015;20(4):531-536. **12**. Østergaard H, Bjelke JR, Hansen L, et al. Prolonged half-life and preserved enzymatic properties of factor IX selectively PEGylated on native N-glycans in the activation peptide. *Blood*. 2011;118(8):2333-2341. **13.** Alprolix [package insert]. Cambridge, MA: Biogen Inc; 2017. **14.** Rixubis [package insert]. Westlake Village, CA: Baxalta Healthcare Corporation; 2016. **15.** Idelvion [package insert]. Kankakee, IL: CSL Behring LLC; 2017. **16.** Ixinity [package insert]. Berwyn, PA: Aptevo BioTherapeutics LLC; 2016. **17.** Benefix [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals, Inc.; 2017.

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

Scan this code using the camera on your smartphone to find a local representative

For Rep business card

Emili, *whose son,* ***Xander,*** *lives with hemophilia B and takes Rebinyn®.*

rebinyn®
Coagulation Factor IX (Recombinant), GlycoPEGylated

TAKE CONTROL TO A HIGH LEVEL

Greater coverage with the highest activity for the longest time[2,4,a]

High factor activity

17%

sustained after 7 days with a single 40 IU/kg dose[1,b]

Improved PK profile compared with BeneFIX and Alprolix[2,4]

5x

longer half-life compared with BeneFIX[2,c]

P<0.001

4x

greater AUC compared with Alprolix[4,d]

P<0.001

[a]Compared with BeneFIX and Alprolix.[2,4]

[b]Based upon a single initial dose of Rebinyn® 40 IU/kg in a subset of 6 adults upon enrollment in the phase 3 trials. Mean FIX activity was 16.8% (1-stage assay with product-specific standard), incremental recovery was 2.34 IU/dL per IU/kg, and half-life was 83 hours.[1]

[c]Phase 1 study of 15 adults administered single doses of Rebinyn® (25, 50, and 100 IU/kg) and prior product (50 IU/kg). Comparison of incremental recovery (Rebinyn® vs SHL rFIX: 1.31 vs 0.68 IU/dL per IU/kg), half-life (93 vs 19 hours), and AUC (72 vs 7 [U x h/mL]) are for 7 patients using 1-stage assay and product-specific standard. All comparisons were significant (*P*<0.001). Estimated mean activity for Rebinyn® was adjusted to a dose of 50 IU/kg to allow for comparison of dose-dependent parameters.[2]

[d]Based upon a phase 1 study of 15 patients administered a single dose of Rebinyn® 50 IU/kg compared with a single dose of Alprolix 50 IU/kg using both 1-stage and chromogenic assays. The standard Alprolix dose of 50 IU/kg was administered for both products to allow for comparison of dose-dependent parameters; dose-normalized to 50 IU/kg to reflect minor differences in doses administered. Comparisons were significant (*P*<0.001) for both assays; 1-stage results for Rebinyn® vs Alprolix included AUC (96.6 vs 22.0 IU x h/mL), incremental recovery (1.7% vs 0.8% per IU/kg), and FIX at 7 days (19% vs 3%).[4]

- Rebinyn® is not approved for routine prophylaxis
- Animals given repeat doses of Rebinyn® showed accumulation of PEG in the choroid plexus. The potential clinical implications of these animal findings are unknown

INDICATIONS AND USAGE

Rebinyn®, Coagulation Factor IX (Recombinant), GlycoPEGylated, is a recombinant DNA derived coagulation Factor IX concentrate indicated for use in adults and children with hemophilia B for on demand treatment and control of bleeding episodes and perioperative management of bleeding.

Limitations of Use: Rebinyn® is not indicated for routine prophylaxis or for immune tolerance induction in patients with hemophilia B.

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

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