REBINYN® FOR ONCE-WEEKLY PROPHYLAXIS

SELECTED KEY INFORMATION ABOUT REBINYN® AND OTHER PROPHYLAXIS FACTOR IX REPLACEMENTS FOR HEMOPHILIA B

Timothy has severe hemophilia B and uses Rebinyn®.

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 (congenital Factor IX deficiency) for on demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes.

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

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:** Allergic-type hypersensitivity reactions, including anaphylaxis, have occurred with Rebinyn®. 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 Important Safety Information throughout.
Please see full Prescribing Information here.

novo nordisk®

rebinyn®
Coagulation Factor IX (Recombinant), GlycoPEGylated

FIX Product Selected Key Attributes[a]

This chart is not intended to be a comparison of efficacy or safety of any of the products. This chart is not intended to be a complete listing of product attributes. Please refer to each product's Prescribing Information for full details.

FIX Product	Prophylaxis Pediatric Indication <12 years	EHL	Half-life	Prophylactic Dose[i]	Storage at Room Temperature Before Reconstitution	Stability at Room Temperature After Reconstitution	Mixing Device Includes Prefilled Diluent Syringe	Consistent Diluent Volume Across All Vial Sizes
Rebinyn®[1]	✓	✓	115 hours[b]	40 IU/kg once weekly in all ages	Up to 86 °F for up to 6 months	Use within 4 hours	✓	✓
Alprolix®[2]	✓	✓	86 hours[c]	50 IU/kg once weekly or 100 IU/kg every 10 days for patients ≥12 years 60 IU/kg once weekly for patients <12 years	Up to 86 °F for up to 6 months	Use within 3 hours	✓	✓
Idelvion®[3]	✓	✓	104 hours[d]	25-40 IU/kg every 7 days may increase to 50-75 IU/kg every 14 days for patients ≥12 years 40-55 IU/kg every 7 days for patients <12 years	Up to 77 °F	Use within 4 hours		
BeneFIX®[4]	✓		23.8 ± 6.5 hours[e]	100 IU/kg once weekly	Up to 86 °F	Use within 3 hours	✓	✓
Rixubis®[5]	✓		25.4 hours[f]	40-60 IU/kg twice weekly for patients ≥12 years 60-80 IU/kg twice weekly for patients <12 years	Up to 86 °F for up to 36 months	Use within 3 hours		✓
Ixinity®[6]	✓		24 ± 6 hours[g]	40-70 IU/kg twice weekly for patients ≥12 years 35-75 IU/kg twice weekly for patients <12 years	500 IU, 1000 IU, 1500 IU, 2000 IU, and 3000 IU strengths: up to 77 °F 250 IU strength: 36 to 46 °F	Use within 3 hours	✓	✓
Alpha Nine®[7]			21 hours[h]	Calculate dose as described in Prescribing Information. Dosing frequency is variable based on patient response.	Up to 86 °F for up to 1 month	Use within 3 hours		✓

The clinical relevance of these PK differences is unknown.

EHL=extended half-life; PK=pharmacokinetic.

[a]Data current as of January 2025.
[b]Based on analysis using a 1-stage assay in patients N=6, aged ≥18, the half-life at steady state was 115 hours following once-weekly (40 IU/kg) dosing; in patients N=3, aged 13 to 17, the half-life at steady state was 103 hours. Following single-dose administration (40 IU/kg) in the same patient population, the half-life was 83 hours (adults) and 89 hours (adolescents).
[c]Based on analysis using a 1-stage assay in patients N=22, aged ≥18, following single-dose administration (50 IU/kg). The pharmacokinetics after single and repeat dosing (at Week 26) were similar.
[d]Based on analysis using a 1-stage assay in patients N=47, aged ≥18, following single-dose administration (50 IU/kg). Pharmacokinetic parameters following single or repeat dosing for up to 30 weeks were similar.
[e]Based on a pharmacokinetic study in previously treated patients N=23, aged ≥12, after repeated administration for 6 months (75 IU/kg).
[f]Based on a pharmacokinetic evaluation N=23, aged ≥12, following repeat dosing for routine prophylaxis (mean dose=74.6 IU/kg).
[g]Based on pharmacokinetic studies, N=14, aged ≥12, following repeat dosing after routine treatment for a median of 5.8 months. Repeat dosing did not impact the pharmacokinetics.
[h]Following a single-dose administration (40 to 50 IU/kg), N=18 patients.
[i]Adjust dosing regimen based on individual response.

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

- **Inhibitors:** The formation of inhibitors (neutralizing antibodies) to Factor IX has occurred following Rebinyn®. If expected plasma factor IX activity levels are not attained, or if bleeding is not controlled as expected with the administered dose, perform an assay that measures Factor IX inhibitor concentration. Monitor all patients using clinical observations and laboratory tests for the development of inhibitors. Factor IX activity assay results may vary with the type of activated partial thromboplastin time reagent used.

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Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

- **Thrombotic Events:** The use of Factor IX-containing products has been associated with thromboembolic 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:** 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.

Adverse Reactions

- The most common adverse reactions reported in previously treated patients in clinical trials (≥1%) were itching and injection site reactions. The most common adverse reactions (≥1%) in previously untreated patients reported in clinical trials were rash, FIX inhibitors, hypersensitivity, itching, injection site reaction, and anaphylactic reaction.
- Animals administered Rebinyn® showed accumulation of PEG in the choroid plexus, pituitary, circumventricular organs, and cranial motor neurons. The potential clinical implications of these animal findings are unknown. Consider whether the patient is vulnerable to cognitive impairment, such as infants and children who have developing brains, and patients who are cognitively impaired.

Please see Important Safety Information throughout.

Please see full Prescribing Information here.

References: 1. Rebinyn [package insert]. Plainsboro, NJ: Novo Nordisk Inc. **2.** Alprolix®. Package Insert. Bioverativ Therapeutics Inc; 2023. **3.** Idelvion®. Package Insert. CSL Behring LLC; 2023. **4.** BeneFIX®. Package Insert. Wyeth Pharmaceuticals LLC; 2021. **5.** Rixubis®. Package Insert. Baxalta US Inc; 2023. **6.** Ixinity®. Package Insert. Medexus Pharma Inc; 2024. **7.** Alpha Nine®. Package Insert. Grifols Biologicals LLC; 2022.

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