Novo Nordisk Lab Program

rebinyn®
Coagulation Factor IX (Recombinant), GlycoPEGylated

Laboratory Services

- **FIX Activity Levels:** 48 hours (received Mon–Thu); 72 hours (received Fri–Sun)
- **Heat-Modified Bethesda Assay:** 7 days (72 hours expedited upon request)

Phlebotomy Services (convenient access to ~1700 local LabCorp Patient Service Centers)

For questions, contact Patrice Roberge, LabCorp Project Manager
Email: robergp@LabCorp.com **Phone: 651-628-6179**

Practice and Prescribers	
Practice/center name	
Address	
Practitioner names	
Office Contact (for results or questions on prescriptions)	
Name	
Phone	
Fax number (for results)	
Email	
Current LabCorp account #	
Draw preference	❑ On-site draw ❑ LabCorp PSC directory

By signing below, the practice/center noted above agrees to activate a special dedicated LabCorp account to allow for participation in the Novo Nordisk–sponsored laboratory program for patients treated with Rebinyn® administered through LabCorp/Colorado Coagulation. Rebinyn® FIX activity levels and inhibitor testing will be available free of charge to patients who are currently prescribed Rebinyn®, using validated assays in compliance with CAP/CLIA regulations. The practice/center will be able to directly submit samples or have them drawn at any local LabCorp phlebotomy locations throughout the US at no charge to the patient. All results will be reported back to the practice/center through the dedicated LabCorp account. No patient information will be shared with Novo Nordisk. Activating the LabCorp account for participation will not result in inclusion in any Novo Nordisk databases, or as a basis for any promotional activities.

Signature			
Name		Date	

Please submit forms by email to FIXLabSupport@LabCorp.com

Factor IX activity assay results may be significantly affected by the type of aPTT reagent used, which can result in over- or underestimation of FIX activity. Avoid the use of silica-based reagents, as some may overestimate the activity of Rebinyn®. If monitoring of FIX is performed, use a chromogenic assay or selected one-stage clotting assay validated for use with Rebinyn®. If a validated assay is not available locally, then use of a reference laboratory is recommended. If bleeding is not controlled with the recommended dose of Rebinyn®, or if the expected FIX activity levels in plasma are not attained, then perform a Bethesda assay to determine if FIX inhibitors are present.

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 on the back.
Please see accompanying Prescribing Information.

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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.
- 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.
- 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.

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 accompanying Prescribing Information.

Novo Nordisk Inc., 800 Scudders Mill Road, Plainsboro, New Jersey 08536 U.S.A.

novo nordisk®