Novo Nordisk Lab Program

esperoct®
antihemophilic factor (recombinant), glycopegylated-exei

Laboratory Services

- **FVIII Activity Levels:** 48-72 hours
- **Factor VIII Nijmegen Bethesda Assay:** 7-day turnaround time

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

For questions, contact by email: FVIIILabSupport@Labcorp.com

Practice and Ordering Practitioners	
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/Colorado Coagulation account to allow for participation in the Novo Nordisk–sponsored laboratory program for patients treated with Esperoct®. Esperoct® FVIII activity levels and inhibitor testing will be available free of charge to patients who are currently prescribed Esperoct®, using validated assays, performed at Labcorp/Colorado Coagulation, 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 through the dedicated Labcorp account. All results will be reported back to the practice/center through the dedicated Labcorp account. 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 FVIIILabSupport@Labcorp.com

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

INDICATIONS AND USAGE
Esperoct® [antihemophilic factor (recombinant), glycopegylated-exei] is indicated for use in adults and children with hemophilia A for on-demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes

- Esperoct® is not indicated for the treatment of von Willebrand disease

Please see Important Safety Information on the back.
Click here for Prescribing Information.

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IMPORTANT SAFETY INFORMATION

Contraindications

- Do not use in patients who have known hypersensitivity to Esperoct® or its components, including hamster proteins

Warnings and Precautions

- Hypersensitivity reactions, including anaphylaxis, may occur. Should hypersensitivity reactions occur, discontinue Esperoct® and administer appropriate treatment
- Development of neutralizing antibodies (inhibitors) has occurred. Perform an assay that measures Factor VIII inhibitor concentration if bleeding is not controlled with the recommended dose of Esperoct® or if the expected plasma Factor VIII activity levels are not attained
- Temporary decrease in Factor VIII incremental recovery (IR) has been observed after Esperoct® infusion, within the first 5 exposure days, in previously untreated patients (PUPs) <6 years of age. During the decreased IR period, these subjects may have an increased bleeding tendency. If bleeding is not controlled with the recommended dose of Esperoct® and/or the expected Factor VIII activity levels are not attained and Factor VIII inhibitors are not detected, consider adjusting the dose, dosing frequency, or discontinuing Esperoct®

Adverse Reactions

- The most frequently reported adverse reactions in clinical trials (≥1%) were rash, redness, itching (pruritus), and injection site reactions. Additional frequently reported adverse reactions (≥1%) in PUPs included Factor VIII inhibition and hypersensitivity.

Click here for Prescribing Information.

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

novo nordisk®