Novo Nordisk Lab Program

tretten®
Coagulation Factor XIII A-Subunit (Recombinant)

FXIII Diagnostic Laboratory Services

- **FXIII Activity level** (Berichrom FXIII)
- **FXIII A-subunit antigen** (ELISA) assays
- **FXIII Inhibitor screen** (Berichrom mixing study)
- **FXIII Genotype** (FXIII A and B gene)

Shipping materials available

Practice and Ordering Practitioners	
Practice/Center Name	
Address	
Practitioner Name and NPI	
Office Contact (for questions about testing)	
Name	
Phone	
Fax (for results)	
Email	

By signing below, the practice/center noted above agrees to activate a special dedicated Esoterix Colorado Coagulation account to allow for participation in the Novo Nordisk-sponsored laboratory program administered through Esoterix Colorado Coagulation for patients prescribed Tretten®. FXIII activity (Berichrom), A-subunit testing (ELISA, genotype), and inhibitor screening will be available free of charge to patients to confirm congenital FXIII A-subunit deficiency prior to filling a prescription for Tretten® using validated assays in compliance with CAP/CLIA regulations. The practice/center will be able to directly submit samples using a courier service that is arranged by Esoterix at no charge. All Novo Nordisk-sponsored testing must be ordered, and will be reported, through the dedicated Esoterix Colorado Coagulation account. Activating the Esoterix Colorado Coagulation 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 Esoterix@LabCorp.com

For further information about the Novo Nordisk Lab Program, contact your Novo Nordisk representative.

Indications and Usage

Tretten®, (Coagulation Factor XIII A-Subunit [Recombinant]), is indicated for routine prophylaxis of bleeding in patients with congenital factor XIII A-subunit deficiency.

Tretten® is not for use in patients with congenital Factor XIII B-subunit deficiency.

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

The International Society of Thrombosis and Haemostasis (ISTH) Guidelines for Diagnosis and Classification of FXIII Deficiencies recommend evaluation to include a quantitative functional assay, measurement of FXIII A and B antigens, detection of antibodies, and evaluation of the molecular genetic defect.

Kohler HP, Ichinose A, Seitz R, Ariens RAS, Muszbek L, on behalf of the Factor XIII and Fibrinogen SSC Subcommittee of the ISTH. Diagnosis and classification of factor XIII deficiencies. J Thromb Haemost. 2011; 9(7):1404-1406.

Important Safety Information

Tretten® is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients.

Tretten® may cause allergic reactions. If signs or symptoms of anaphylaxis or hypersensitivity reactions (including urticaria, rash, tightness of the chest, wheezing, hypotension) occur, discontinue immediately and institute appropriate treatment.

Thromboembolic complications may occur. Monitor patients with conditions that predispose to thrombosis for signs and symptoms of thrombosis after administration of Tretten®.

Inhibitory antibodies may occur with Tretten®. Patients with inhibitory antibodies may manifest as an inadequate response to treatment. If expected plasma FXIII activity levels are not attained, or if breakthrough bleeding occurs while receiving prophylaxis, perform an assay that measures FXIII inhibitory antibody concentrations.

The most common adverse reactions reported in clinical trials (≥1%) were headache, pain in the extremities, pain at injection site, and increase in fibrin D dimer levels.

Thrombosis may occur if Tretten® is administered concomitantly with Factor VIIa.

There are no adequate and well-controlled studies using Tretten® in pregnant women to determine whether there is a drug-associated risk. Animal reproduction studies have not been conducted with Tretten®.

Click here for Prescribing Information.

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

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tretten®
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