ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

Tretten®
Recombinant Factor XIII

APPLICABILITY: This document applies to all APL, AHS, Covenant Health, and all other health care professionals involved in the transfusion of blood components and products in Alberta.	***Other Names:*** *recombinant Factor XIII (A subunit), catridecacog* ***Company:*** *Novo Nordisk Canada Inc.* ***Class:*** *Manufactured recombinant product*

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**IV Infusion**	**Continuous Infusion**	**SC**	**IM**	**OTHER**
Acceptable Routes*	Yes**	No	No	No	No	N/A

*** Professionals performing these restricted activities have received authorization from their regulatory college and have the knowledge and skill to perform the skill competently.**
**** Direct IV Administration of Blood Products may be performed by professionals per the Transfusion of Blood Components and Products Learning Module. Not to be confused with medication administration.**

DESCRIPTION:

- Tretten® is a recombinant human FXIII homodimer consisting of two FXIII A-subunits.
- Manufactured as a soluble protein in yeast. No animal or human derived proteins are used in manufacturing process.
- Available in 2500 IU (15 mg) single use vials of white lyophilized powder.
- After reconstitution with 3.2mL sterile water for injection, catridecacog concentration is approximately 833 IU/mL (5 mg/mL). If the reconstituted solution is further diluted with 0.9% sodium chloride for patients weighing less than 24kg, the concentration of the solution is approximately 299 IU/mL (1.8 mg/mL).
- Reconstituted solution is clear and colourless.
- Also contains: L-histidine, polysorbate 20, sodium chloride, and sucrose.
- Latex-free.

AVAILABILITY:

- Supplied by Canadian Blood Services.
- Contact your local laboratory/transfusion service regarding stock availability on site.

INDICATIONS:

- For routine prophylaxis of bleeding episodes in patients with congenital Factor XIII A-subunit deficiency.
- Clinical trials on the treatment of acute bleeds or breakthrough bleeds with Tretten® have not occurred.

CONTRAINDICATIONS:

- History of hypersensitivity reactions to the product or any of its components. Refer to product insert.
- Prophylactic treatment of bleeding in patients with congenital factor XIII B-subunit deficiency.

WARNINGS:

- Caution should be exercised in patients where predisposition to thrombosis is present due to fibrin-stabilizing effect of Tretten®.
- Patients should be advised to store the product according to the described storage conditions (see STORAGE & STABILITY OF PRODUCT). Incorrect storage of the product after reconstitution must be avoided as it may result in loss of sterility and in increased levels of non-proteolytically activated rFXIII, which may in turn increase the risk of thrombosis.

DOSE (Refer to Product Insert):

- Dose to be determined by the most responsible health practitioner (MHRP) only after consult with hematologist or bleeding disorders clinic.
- Manufacturer recommended dose: 35 IU/kg approximately once monthly.

ADMINISTRATION:

Confirm written (signed) consent has been obtained and documented prior to requesting blood component from lab/transfusion service where possible.

Pre-Infusion:

- Ensure recent patient weight is on file.
- Ensure pertinent labs are available as required.
- Ensure any ordered premedications have been given.
- Perform the appropriate pre-transfusion checks per *AHS Transfusion of Blood Components and Blood Products Policy.*
- Report any new onset acute illness to the authorized prescriber prior to commencing infusion.

Access: Tretten® can be given via a peripheral or central venous access site.

Reconstitution:

- See *Tretten® Reconstitution Instructions*
- See special dilution steps in the Reconstitution Instructions for patients weighing less than 24 kg.
- Use the supplies and diluent contained in the box.

Compatible IV Solutions:

- Normal saline

Administration Supplies:

- Infusion set (not included with product)
- Sterile plastic luer lock syringe, large enough to contain dose

Administration:

- Visually inspect prior to administration. Do not use solutions that are cloudy, have deposits, or are not colourless
- Give immediately after reconstitution (within 3 hours).
- Separate line infusion.
- No other drugs or IV solutions can be co-administered in the same line while Tretten® is being infused.
- Discard any unused Tretten®.
- **Administration Rate:**
  - Administration rate should be specified by the MRHP after patient assessment.
  - Recommended administration as a slow bolus infusion at a maximum rate of 1-2 mL per minute.

NURSING IMPLICATIONS:

Patient Monitoring:

- Vital Signs: Pre-administration**,** on completion of dose, and as patient condition requires.

Patients receiving blood product transfusions must be observed closely for signs of any unexpected or untoward reactions. These reactions may occur during or after the infusion of blood or blood products. For follow up instructions to a transfusion reaction, go to: www.albertahealthservices.ca/lab/page4240.aspx

Documentation:

- Ensure documentation is completed as per the *AHS Transfusion of Blood Components and Blood Products Policy.*
- Patient tolerability should also be documented in appropriate flow chart or clinical record (electronic or paper).
- Document vital signs in the appropriate flow chart or clinical record (electronic or paper)
- Provide patient notification documentation where required.

POTENTIAL HAZARDS WITH PARENTERAL ADMINISTRATION:

- Potential adverse events related to a blood product transfusion range in severity from minor with no sequelae to life-threatening.
- All adverse events occurring during a transfusion should be evaluated to determine whether or not the transfusion can be safely continued/restarted.
- All adverse events suspected to be related to a product transfusion (whether during or after a transfusion) must be reported to your local transfusion service.

Side Effects: - Flushing - Headache - Nausea - Itching and redness at the venipuncture site		**Action:** Slow rate of infusion
Potential Allergic Reaction: - Stuffy nose - Hives/severe itching - Cough - Chest pain - Wheezing - Facial swelling		**Action:** **STOP** infusion **IMMEDIATELY** and contact physician

STORAGE & STABILITY:

- Store at 2-8°C.
- Reconstituted product may be stored in the **vial.** Do not store in syringes.
  - Up to 3h at room temperature.
  - Up to 24h at 2ºC - 8ºC.
- Do not freeze.
- Protect from light.
- Do not use expired product.

CONTACT INFORMATION:

Approved By: APL Transfusion Medicine Discipline Council
For questions or comments please contact: Transfusion.SafetyTeam@aplabs.ca

REFERENCES:

Novo Nordisk Canada Inc. June 2017. Tretten® Product Monograph. SCN 203628. [accessed 20211126] https://www.novonordisk.ca/content/dam/nncorp/ca/en/products/tretten-product-monograph.pdf

PS-59 Transfusion of Blood Components and Products Policy. Alberta Health Services. Jan 2017.