Alberta Health Services

This document applies to all Covenant and AHS sites.

Tretten® - Recombinant Factor XIII

Class: *Coagulation factor, manufactured recombinant product*

OTHER NAMES: Recombinant Factor XIII (A-subunit), Catridecacog

Company: Novo Nordisk Canada Inc.

	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.**

**** Transfusion of Blood Components and Products Learning Module Section Three: Direct IV Administration of Blood Products. RNs may administer direct IV blood products. Not to be confused with medication administration**

DESCRIPTION OF PRODUCT:

- 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.
- Comes as a white lyophilized powder and is available in 2500 IU vial size.
- Also contains: L-histidine, polysorbate 20, sodium chloride, and sucrose.
- **Latex-free**

AVAILABILITY:

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

INDICATIONS FOR USE:

- 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:

- Known hypersensitivity to this drug, or any ingredients in the formulation (see Description of Product).
- Should not be used in patients to treat congenital FXIII 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):

- Consult with Hematologist or local bleeding disorders clinic.

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 and pertinent labs are available. Perform the appropriate pre-transfusion checks per protocol.

Access: Tretten® can be given via CVC, PICC, Port-a-Cath®, or peripheral IV line.

Reconstitution Supplies:

- 2500 IU vial of lyophilized recombinant FXIII
- 3.2 mL sterile water for injection (diluent)
- Sterile vial adapter for reconstitution
- Antiseptic swabs

} Contained in box

Administration Supplies:

- Sterile plastic Luer lock syringe (large enough to contain dose)
- Butterfly infusion set (or other appropriate infusion set), if required

Reconstitution:

- Refer to reconstitution steps https://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-tm-tretten-reconst-inst.pdf
- See special instructions in reconstitution steps for patients weighing less than 24 kg.
- Use the supplies and diluent contained in the box to reconstitute.
- **DO NOT** further dilute in any IV solutions.

Administration:

- Give immediately after reconstitution – should be used within 3h of reconstitution.
- **DO NOT** freeze after reconstitution.
- **Can be stored up to 24h at 2ºC - 8ºC if not used immediately.**
- Separate line infusion.
- Direct IV administration only
- 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:

- Slow IV bolus, **maximum 1-2 mL/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, see: http://www.albertahealthservices.ca/4240.asp

Documentation:

- The transfusion documentation should be double signed (where required) to indicate infusion. Document start and stop date and time of transfusion.
- Assessment of patient tolerability should also be documented in appropriate flow chart or clinical record (electronic or paper) as 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) should be reported to your local transfusion service.

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

STORAGE & STABILITY OF PRODUCT:

- Stored at 2-8°C.
- **Do not freeze**.
- Protect from light.
- Use immediately (within 3 hours) following reconstitution (see WARNINGS)

COMMENTS:

Date Effective: 13 Sept 2019
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Approved By: APL Transfusion Medicine Discipline Council
Document#: PTMGNR00055
References: Tretten® product monograph.
For comments or questions about this document, please contact Transfusion.SafetyTeam@ahs.ca.

LINK to WEBSITE:

http://www.novonordisk.ca