Alberta Health Services

This document applies to all Covenant and AHS sites.

REBINYN®

Class: *Manufactured recombinant product*

OTHER NAMES: recombinant Factor IX pegylated, nonacog beta pegol

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:

- REBINYN® contains recombinant Factor IX.
- Supplied in 500, 1000, 2000 IU single use vials as a white to off-white lyophilized, sterile, non-pyrogenic preservative free powder, along with 4ml histidine solvent in a prefilled syringe.
- When reconstituted, REBINYN® is used as a replacement therapy to increase plasma levels of factor IX activity, enabling a temporary correction of factor deficiency and bleeding tendency.

AVAILABILITY:

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

INDICATIONS FOR USE:

- Indicated in adults and children with hemophilia B (congenital factor IX deficiency or Christmas disease) for:
  - Control and prevention of bleeding episodes (e.g. in trauma or procedures with increased risk of bleeding)
- Indicated in adults with hemophilia B (congenital factor IX deficiency or Christmas disease) for:
  - Routine prophylactic treatment to prevent or reduce the frequency of bleeding episodes
  - Perioperative management (surgical prophylaxis)

CONTRAINDICATIONS:

- Known hypersensitivity or previous manifestations of severe reactions to any of the constituents in product (including hamster protein).
- Not indicated for immune tolerance induction (ITI).

WARNINGS:

- Clinical response to REBINYN® may vary. If bleeding is not controlled with recommended dose, a plasma level of factor IX should be determined, and sufficient dose administered to achieve clinical response. Presence of an inhibitor should be suspected if patient's plasma level fails to increase or bleeding is not controlled after administration.
- The use of Factor IX containing products has been associated with the development of thromboembolic complications. Monitor patients on REBINYN® for early signs of vascular thrombotic events.

DOSE:

- **Recommended Dosing for Routine Prophylaxis in Adults (18 and older):**
  - 40 IU/kg once weekly
  - Routine monitoring of FIX activity for the purpose of dose monitoring is not required
  - Patients who miss their dose are advised to take their dose upon discovery, but avoid a double-dose.
- **Recommended Dosing for Control of Bleeding Episodes in Adults, Adolescents and Children:**
  - Minor and Moderate bleeding: 40 IU/kg. Single dose should be sufficient. Additional doses can be given.
  - Major bleeding: 80 IU/kg
- **Recommended Dosing for Perioperative Management in Adults:**
  - Minor operations (including uncomplicated dental extraction): 40 IU/kg (See product insert)
  - Major: 40-80 IU/kg (See product insert)

**** Consult with Hematologist or 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: REBINYN® can be given via CVC, PICC, Port-a-Cath®, or peripheral IV line

Reconstitution Supplies:

- REBINYN®, lyophilized in single dose vial
- Prefilled syringe with 4ml histidine diluent
- Vial adapter

} Contained in box

Administration Supplies:

- **For direct IV administration:**
  - Sterile infusion set (provided in kit), if no established IV access
  - Plastic syringe (10mL, or large enough to contain entire dose)Alcohol swabs

Reconstitution: Refer to reconstitution steps with vial adapter using following link:
http://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-tm-rebinyn-reconst.pdf

Administration:

- Intended for Direct IV administration.
- **DO NOT** mix with other drugs or IV solutions.

*** Included glass syringe is incompatible with ICU Medical MicroClave® Neutral Connector. Draw up reconstituted product with a sterile plastic luer-lock syringe for administration.***

Administration rate:

- Direct IV at rate ordered by authorized prescriber or local bleeding disorders clinic (**4mL/minute maximum**), or determined by patient's comfort level. Maximum rate = 4mL/minute

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.
- **The most common adverse reactions are pyrexia, injection site reactions, headache, hypertension, hypotension, nausea, vomiting, pain, edema, and rash. Monitor for signs and symptoms of thrombosis.**

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

NURSING IMPLICATIONS:

Patient Monitoring:

- Vital Signs: Pre-administration**,** on completion of dose, and as the patient condition requires.
- If the patient has experienced previous adverse reaction to this blood product transfusion, or this is the first transfusion of this blood product for patient, the patient should be monitored for 30-60 minutes post-dose.

Patients receiving 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 to a transfusion reaction see: http://www.albertahealthservices.ca/4240.asp. Notify the transfusion service as soon as possible that an adverse reaction has occurred.

Documentation:

- Ensure documentation is completed as per the AHS *Transfusion of Blood Components and Products* procedure
- Assessment of patient tolerability should be documented in appropriate flow chart or clinical record (electronic or paper) as required.

STORAGE & STABILITY OF PRODUCT:

- Stored at 2-8°C. **Do not freeze**.
- Product may be stored at room temperature (up to 30°C) for a single 6 month period (at the end of 6 month period, product must be discarded if not used). Do not use past expiry date. Do not return to refrigerator storage once removed.
- Keep protected from light.
- Give as soon as possible (within 4 hrs) of reconstitution. Reconstituted solution can be stored for up to 24 hours at 2-8 ^{o}C in the vial.

COMMENTS:

Date Effective: 13 Sept 2019
Version 1.1
Approved By: APL Transfusion Medicine Discipline Council
Document Number: PTMGNR00058
For questions or comments about this document, please contact Transfusion.SafetyTeam@ahs.ca

REFERENCES

REBINYN® product monograph SCN 201114

LINK to WEBSITE for PRESCRIBING INFORMATION:

http://www.novonordisk.ca