ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

Rebinyn®
Recombinant Factor IX

APPLICABILITY: This document applies to 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 IX pegylated, nonacog beta ***Company:*** *Novo Nordisk Canada* ***Class:*** *Manufactured recombinant product*

In the event of discrepancy between APL Monograph and Manufacturer's documentation or patient resources, the APL Monograph will take precedence.

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

* Administration of blood components and blood products is a restricted activity. For specific conditions that apply to a profession's authorization to administer blood components and blood products, consult the applicable discipline-specific regulation under the Health Professions Act (Alberta). Health care professionals with this authorization require the applicable education, training and competency.
** Direct IV administration of blood products may be performed by health care professionals that have authorization of administration of blood products within their scope of practice.

DESCRIPTION:

- Rebinyn® is a lyophilized, sterile, non-pyrogenic, purified Factor IX manufactured by recombinant DNA technology.
- Viral inactivation/removal steps include detergent treatment and 20nm filtration.
- Supplied in 500, 1000, 2000 or 3000 IU single-use vials.
- Vials are reconstituted with 4ml histidine solvent, supplied in a prefilled syringe.
- Lyophilized product is white to off-white.
- The 500IU, 1000IU and 2000IU solution is a clear and colourless liquid, and the 3000 IU solution is a clear and colourless to slightly yellow liquid. Reconstituted solution is free from visible particles.
- Also contains sodium chloride, sucrose, and histidine, mannitol, and polysorbate 80.
- Preservative Free.
- Latex-free.

AVAILABILITY:

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

INDICATIONS FOR USE:

- 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.
- Indicated in adults and children with hemophilia B (congenital factor IX deficiency or Christmas disease) for:
  - routine prophylaxis to prevent or reduce the frequency of bleeding episodes
  - control and prevention of bleeding episodes
  - control and prevention of bleeding in the perioperative setting

CONTRAINDICATIONS:

- Patients who are hypersensitive to any ingredient in the formulation or component of the container.
- 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:

- Dose to be determined by the most responsible health practitioner (MHRP) only after consult with hematologist or bleeding disorders clinic.
- Refer to patient's care plan or Factor First card, if available.
- If neither are available, consult with bleeding disorders clinic or transfusion medicine physician.
- The dose recommendations in children are the same as for adults.
- **Manufacturer Recommended Dosing:** (See product insert)
  - **Routine Prophylaxis:**
    - 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.
  - **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. Additional doses of 40IU/kg can be given.
  - **Perioperative Management in Adults:**
    - Minor surgery (including uncomplicated dental extraction): 40 IU/kg
    - Major surgery: 80 IU/kg pre-operative dose. Consider two repeated doses of 40IU/kg (in 1-3 day intervals) within the first week after surgery. The frequency of dosing in the post-surgical period may be extended to once weekly after the first week until bleeding stops, and healing is achieved.

ADMINISTRATION:

Confirm consent has been obtained and documented prior to requesting blood components or products (human-source) from lab/transfusion service where possible.

Pre-Infusion:

- Ensure recent patient weight and height is on file.
- Ensure pertinent labs are available as required.
- Ensure any ordered premedications have been given.
- Perform 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: Rebinyn® can be given via peripheral or central venous access site.

Reconstitution Supplies:

- Rebinyn® product (lyophilized powder)
- 4ml histidine diluent (prefilled syringe - included with product)
- Vial adapter (included with product)

Reconstitution:

- Bring the product and diluent to room temperature before reconstitution.
- Refer to Prefilled Syringe Reconstitution Instructions.
- Do not store in syringes.

Compatible Solutions:

- N/A
- Do not mix with other products, medications, or solutions.

Administration Supplies:

- Sterile infusion set (included with product), if no established IV access
- Sterile plastic luer-lock syringe (large enough to contain dose)
- Alcohol swabs

***Note:** The pre-filled glass syringe with diluent used to reconstitute and administer product may not be compatible with all needleless connectors for intravenous catheters (e.g. ICU Medical MicroClave® Neutral Connector). You may need to withdraw reconstituted product into a sterile plastic syringe with a standard luer-lock connector. Ensure the vial adapter is used when withdrawing the solution from the vial into the syringe.

Administration:

- Inspect for particulate matter and discoloration prior to administration. Do not use solutions that are visibly cloudy or have deposits.
- Intended for Direct IV administration.
- Give as soon as possible (within 4 hrs) of reconstitution.

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

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.

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: Transfusion Reactions | Alberta Health Services. 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 Policy.
- Start and stop time of infusion and assessment of patient tolerability should be documented in appropriate flow chart or clinical record (electronic or paper).
- Document vital signs as required in the appropriate flow chart or clinical record (electronic or paper).
- Provide patient notification of transfusion 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) should be reported to your local transfusion service.
- The most common adverse reactions to Rebinyn® 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 - Fainting	**Action:** **STOP** infusion **IMMEDIATELY** and contact physician

STORAGE & STABILITY:

- Store at 2-8°C until expiry.
- May be stored for up to 6 months at room temperature (up to 30°C). Product expires after 6 months RT storage. Once the product has been taken out of the refrigerator it must not be returned to the refrigerator.
- Reconstituted solution can be stored for up to 24 hours at 2-8°C in the vial.
- Do not store in syringes.
- Protect from light.

CONTACT INFORMATION:

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

REFERENCES

Novo Nordisk Canada Inc. November 2017 (revision date 22November2022) Rebinyn Product Monograph. Submission Control No 236051 [Accessed04Jan2024].
rebinyn-product-monograph.pdf (novonordisk.ca)

PS-59 AHS Transfusion of Blood Components and Blood Products Policy.