BeneFIX®

APPLICABILITY: This document applies to 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, nonacog alfa* ***Company:*** *Pfizer Canada Inc.* ***Class:*** *Factor IX concentrate, manufactured recombinant product*

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**IV Infusion**	**Continuous Infusion**	**SC**	**IM**	**OTHER**
Acceptable Routes*	Yes**	Yes	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:

- BeneFIX® is a sterile, nonpyrogenic, lyophilized powder of recombinant Factor IX.
- Available in vial sizes of 500 IU, 1000 IU, 2000 IU, and 3000IU. The reconstituted product contains approximately 100 IU/mL, 200 IU/mL, 400 IU/mL, and 600UL/mL respectively.
- Not derived from human blood and contains no preservatives.
- Also contains glycine, sucrose, L-histidine, polysorbate 80, and sodium chloride.
- **Latex-free**

AVAILABILITY:

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

INDICATIONS FOR USE:

- For the control and prevention of bleeding episodes in patients with hemophilia B; including the perioperative management of patients with hemophilia B.
- NOT indicated for the treatment of:
  - other factor deficiencies (e.g. factors II, VII, and X) or for hemophilia A patients with inhibitors to factor VIII
  - reversal of coumarin-induced anticoagulation
  - treatment of bleeding due to low levels of liver-dependent coagulation factors

CONTRAINDICATIONS:

- Known hypersensitivity to hamster proteins.
- Known hypersensitivity to BeneFIX® or any of the constituents in the formulation of BeneFIX®.

WARNINGS:

- Caution should be exercised in patients with liver disease, post-operative patients, neonates, and to patients at risk of developing thromboembolic phenomena or DIC due to the potential risk of thromboembolic complications.

DOSE (Refer to Product Insert):

- Dosage must be individualized based on severity of Factor IX deficiency, location and extent of bleeding, and the patient's clinical condition. 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: BeneFIX® can be given via CVC, PICC, Port-a-Cath®, or peripheral IV line.

Reconstitution Supplies:

- Vial of lyophilized recombinant Factor IX
- 1.5 mL diluent syringe and plunger rod
- Vial adapter with in-line filter
- Butterfly infusion set
- Alcohol swabs
- Sterile gauze
- Adhesive bandage

} Contained in box

- Sterile Luer lock syringe (large enough to fit multivial dose)

Administration Supplies:

- **For direct IV administration:**
  - Sterile plastic Luer lock syringe (large enough to contain dose)
- **For IV infusion:**
  - IV administration set
  - Syringe pump

Reconstitution: Refer to reconstitution steps see: http://www.albertahealthservices/labservices/wf-lab-clin-tm-benefix-reconst-inst.pdf

- Use the supplies and diluent contained in the box to reconstitute.
- **DO NOT** further dilute in any IV solutions

Administration:

- Give within 3 hours of reconstitution. **DO NOT** refrigerate after reconstitution.
- **Administration rate:** should be given over several minutes, and should be determined by the patients comfort level.
- Blood should not enter the syringe, as it causes red cell agglutination. If it does occur, discard all material and start over with a new package.
- Dose issued may slightly vary (+/- 10%) from dose ordered based on vial sizing.

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.
- Start and stop time of infusion and 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.
- Patients using BeneFIX® should be monitored for development of factor IX inhibitors.

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 2-30°C.
- **Do not freeze**.

COMMENTS:

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For questions or comments regarding this document, please contact Transfusion.SafetyTeam@ahs.ca

REFERENCES:

BeneFIX® product monograph available at http://www.pfizer.ca/