Alberta Health Services

This document applies to all Covenant and AHS sites.

FEIBA™NF – Anti-Inhibitor Coagulant Complex

Class: *Human plasma fraction with Factor VIII inhibitor bypassing activity*

OTHER NAMES: Anti-inhibitor Coagulant Complex, Vapor Heated and Nanofiltered

Company: Baxter

	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.**

DESCRIPTION OF PRODUCT:

- A freeze-dried sterile human plasma fraction containing factor VIII-inhibitor bypassing activity.
- Contains factors II, IX, and X, mainly non-activated, and factor VII mainly in the activated form.
- Contains equal units of factor VIII-inhibitor bypassing activity and prothrombin complex factors.
- Factor VIII-inhibitor bypassing activity is expressed in arbitrary units- FEIBA units. One FEIBA Unit of activity is the amount of FEIBA™ NF that shortens the APTT of a high-titer factor VIII inhibitor reference plasma to 50% of the blank value.
- Viral reduction steps include vapor pressure, heating and nanofiltration.
- Available in single-use vials of 400-1200 Units/20 mL or 1750-3250 Units/50 mL. Actual Feiba units are indicated on vial.
- **Latex-free**

AVAILABILITY

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

INDICATIONS FOR USE:

- Management of spontaneous bleeding episodes
- Prophylaxis for surgical procedures in hemophilia A and B patients with factor VIII inhibitors.
- Cases have been described where FEIBA was used in the treatment of non-hemophiliacs with acquired inhibitors to Factors VIII, XI and XII, as well as in the treatment of a von Willebrand's patient with an inhibitor. (See package insert for details).

CONTRAINDICATIONS:

- Patients with normal coagulation mechanism.
- Consumption coagulopathy or abnormal fibrinolysis.

WARNINGS:

- In patients with a tentative or definitive diagnosis of coronary heart disease, as well as patients with acute thrombosis and/or embolism, FEIBA™ NF is only indicated in life-threatening bleeding events.
- Although rare, myocardial infarction, pulmonary embolism, or thrombosis may occur after high doses and/or prolonged administration of FEIBA™ NF particularly in patients with predisposing risk factors (e.g. liver disease, post operative, infection inflammation etc)
- Not recommended to use antifibrinolytics until 12h after administration of FEIBA™ NF.

DOSE (Refer to Product Insert):

- Dose is patient and indication specific.
- Consult with Hematologist or hemophilia clinic.

ADMINISTRATION:

Ensure patient consent has been obtained prior to requesting blood product 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 nursing protocol.

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

Reconstitution Supplies:

- Vial of FEIBA™ NF lyophilized powder
- Vial of Sterile Water for Injection (diluent)
- BAXJECT II Hi-Flow™ filter transfer device (single use)
- Alcohol swabs

} Contained in box

- Sterile plastic Luer lock syringe (in box, or large enough to contain dose)

Reconstitution: For reconstitution instructions using Baxject II Hi Flow go to:
http://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-tm-baxjectii-inst.pdf

Administration Supplies:

- **For direct IV administration:**
  - Sterile plastic Luer lock syringe (large enough to contain dose)
- **For IV infusion:**
  - IV administration set (either a buretrol, infusion set for syringe pump or minibag with regular infusion set)
  - IV pump or syringe pump as appropriate

Administration:

- Give immediately after reconstitution (within 3 hours). **DO NOT** refrigerate after reconstitution.
- Product must not be further diluted or mixed with other solvents.
- No other drugs or solutions can be co-administered in the same line while FEIBA™ NF is being infused.
- The amount of product received for administration may be 10% lower or higher than the actual dose ordered. Administer the entire dose.

Administration rate: not to exceed 2 Units/kg body weight/minute or as requested by the ordering physician or the bleeding disorders clinic.

Options for IV Infusion:

- **Buretrol:** (In-line or 'add-a-line')
  - **Option 1:** Attach 500-mL normal saline bag to buretrol line. Prime tubing with 35 mL normal saline **(**leave chamber empty) and close clamp between NS and buretrol. Add product to chamber for infusion and infuse product. Flush line at the same rate with 35 mL normal saline at the end of infusion to ensure entire dose has been administered.
  - **Option 2:** Prime buretrol line with product (similar to tPA process). Infuse product. Flush line at the same rate with 35 mL normal saline at the end of infusion.
- **Syringe pump:** Not to exceed 2 units/kg body weight/minute, or rate prescribed by physician or bleeding disorders clinic.
- **Minibag:** Remove all normal saline from a minibag sufficient in size to hold the required volume of product. Replace normal saline with product. Using regular IV tubing, prime line with product. Attach to closest port to patient. Flush with 35 mL normal saline at the end of infusion to ensure entire dose has been administered.

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: 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.
- 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) should 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 - Fainting	**Action** **STOP** infusion **IMMEDIATELY** and contact physician

STORAGE & STABILITY OF PRODUCT:

- Stored at 2-25°C. **Do not freeze**.

COMMENTS:

Date Effective: 29 Apr 2016
Revised Date: 13 Apr 2016
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Approved By: TM Network
Document Number: PTMGNR00021
Reference: FEIBA™ product monograph.
For questions or concerns regarding this document contact transfusion.safetyteam@albertahealthservices.ca

LINK to WEBSITE for PRESCRIBING INFORMATION:

Product monograph available at
http://www.baxter.ca