ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

FEIBA® NF

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:*** *Anti-inhibitor Coagulant Complex* ***Company:*** *Takeda Canada* ***Class:*** *Manufactured blood product, derived from human plasma*

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**IV 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:

- FEIBA® is 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® 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.
- Reconstituted FEIBA® also contains trisodium citrate and sodium chloride.
- Preservative free.
- Latex free.

AVAILABILITY:

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

INDICATIONS:

- Patients with Hemophilia A and B with inhibitors, for:
  - Management of spontaneous bleeding episodes.
  - Surgical interventions.
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children over 6 years of age.
- May be 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 who are hypersensitive to FEIBA®, or any ingredient in formulation or component of the container.
- 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® 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® 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.
- Patients with Factor VIII inhibitor titers greater than 10 B.U. have generally been refractory to treatment with Antihemophilic Factor.

DOSE (Refer to Product Insert):

- Dose is to be determined by the most responsible health practitioner (MRHP) **only** after consult with Hematologist or bleeding disorders clinic.
- Dose is patient and indication specific, and may not correlate to patient's inhibitor titre.
- **On-demand treatment:**
  - 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.

ADMINISTRATION:

Confirm written (signed) consent has been obtained and documented prior to requesting blood components or blood products from the transfusion service/laboratory where possible.

Pre-Infusion:

- Ensure patient height and weight are on file.
- Ensure pertinent labs are available as required.
- Ensure any ordered premedications have been given (antihistamines, antipyretics prn).
- Perform pre-transfusion checks per AHS Transfusion of Blood Component and Blood Products Policy.
- Report any new onset acute illness to the authorized prescriber prior to commencing infusion.

Access:

- FEIBA® can be given via peripheral or central venous access site.

Reconstitution Supplies:

- FEIBA® Product (lyophilized powder)
- Sterile water for injection (included with product)
- BAXJECT II Hi-Flow device (included with product)
- Antiseptic swabs (not included)
- Syringe (included with product)

Reconstitution:

- See Baxject II Hi Flow Reconstitution Instructions
- Bring the diluent to room temperature prior to reconstitution (max 37°C).
- Do not dilute further.
- FEIBA® should be administered as soon as possible (within 3 hours) after reconstitution.
- Do not refrigerate after reconstitution.

Compatible IV Solutions:

- Do not mix with other products, medications, or solutions.
- Normal saline may be used to flush the line.

Administration Supplies:

- Direct IV:
  - Sterile plastic Luer lock syringe (large enough to contain dose)
- IV Infusion:
  - IV administration set (infusion set for syringe pump, or regular infusion set for minibag).
  - IV pump or syringe pump (if required).

Administration:

- The amount of product received for administration may be 10% lower or higher than the actual dose ordered. Administer the entire dose.
- Visually inspect the product prior to administration. Do not use products that are cloudy or contain particulates.
- No other drugs or IV solutions can be co-administered in the same line while FEIBA® is being infused.
- **IV Administration:**
  Option 1: Transfer to Minibag
  - Empty the IV bag and inject reconstituted FEIBA® into the empty bag.
  - Label the bag per the AHS Transfusion of Blood Components and Blood Products Policy
  - Prime the line with FEIBA®.
  - Infuse the prescribed amount at the appropriate rate.
  - Flush using normal saline.

  Option 2: Syringe Pump
  Option 3: Administer via Direct IV. Flush using normal saline.
- **Administration rate:**
  - Administration rate should be specified by the MRHP after patient assessment.
  - Do not exceed 2 units / kg / minute.

NURSING IMPLICATIONS:

Patient Monitoring:

- Vital Signs: Pre-administration**,** on completion of dose, and as patient condition requires.
- Monitor patients receiving FEIBA® for signs and symptoms of thromboembolic events.
- If the patient has experienced a previous adverse reaction to product transfusion, or this is the first transfusion of the product for the patient, monitor for 30 – 60 minutes post.

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/lab/page4240.aspx.

Documentation:

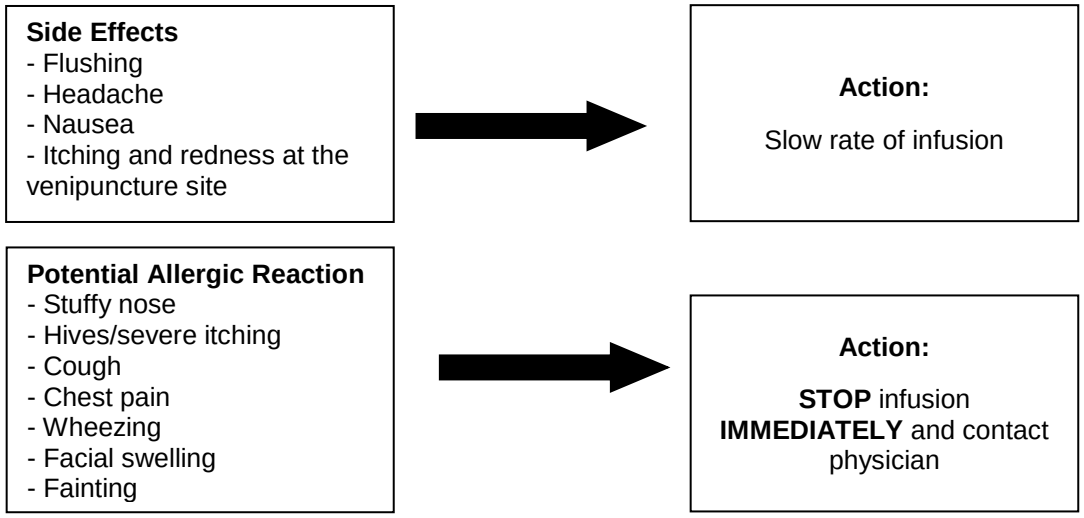
- Complete documentation as per the *AHS Transfusion of Blood Components and Blood Products Policy.*
- Start and stop time of infusion and assessment of patient tolerability should be documented in appropriate flow chart or clinical record (electronic or paper).
- Document vital signs as required in the appropriate flow chart or clinical record (electronic or paper).
- Provide patient notification of transfusion documentation where required.

LABORATORY MONITORING

- Due to the complex mechanism of action, no direct monitoring is available.
- Tests used to control efficacy, such as PTT, do not correlate with clinical improvement. Attempting to normalizing these values by increasing the dose of FEIBA® is strongly discouraged because of the potential hazard of producing DIC by overdosage.
- False positive results in serological tests may occur (e.g. CMV serology, Direct Antiglobulin Test, etc.).
- In case of inadequate response to treatment, a platelet count should be performed. A sufficient number of functionally intact platelets necessary for the efficacy of the product.

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) must be reported to your local transfusion service.
- The most common reactions to FEIBA® are hypersensitivity, dizziness, headache, hypotension, and rash.



STORAGE & STABILITY:

- Store at 2-25°C until expiry.

CONTACT INFORMATION:

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

REFERENCES:

Takeda Canada Inc. December 2020. FEIBA® NF Package Insert. Submission Control No 241701. [Accessed 25Feb22]. https://www.takeda.com/491aab/siteassets/en-ca/home/what-we-do/our-medicines/product-monographs/feiba-nf/feiba-nf-pm-en.pdf
PS-59 AHS Transfusion of Blood Components and Blood Products Policy.