Feiba NF

TRANSFUSION MEDICINE SERVICES

CLASSIFICATION	ALERTS
Antihemolytic Factor VIII Product with inhibitor bypassing activity	Potential risk of thromboembolic complications when used in combination with other factor products

PREPARATION and ADMINISTRATION

Feiba NF is a plasma derived factor concentrate, blood consent IS required.

Reconstitution

Diluent: Sterile water for injection in 10, 20 or 50 mL volume containers.

See pages 3-5 for reconstitution steps -administer within 3 hours of reconstitution

After reconstitution, inspect visually for particulate matter prior to administration

IV Direct	Intermittent Infusion	Continuous Infusion
IV Direct is the recommended route of administration. Professionals performing these restricted activities must have received authorization from their regulatory College and have the knowledge and skill to perform the skill competently Administer dose as reconstituted solution. **Do not exceed an infusion rate of 2 Units FEIBA/kg/minute**. Example: In a patient with a body weight of 75 kg, this corresponds to an infusion rate of 2.5 - 7.5 mL per minute depending on the number of units per vial (actual number of units on vial label).	**IV Bag (large volume pump)** Not Recommended **Syringe (syringe pump)** Not Recommended	**IV Bag (large volume pump)** Not applicable **Syringe (syringe pump)** Not applicable

Requirements and Monitoring

Use with caution in patients at risk of DIC, arterial or venous thrombosis

Baseline vitals before starting infusion. Reassess 15 min after infusion.

Document all vitals taken.

Blood pressure via cuff or arterial line
Temperature
Heart Rate

Respirations Keep unopened back up bag of NS and standard IV tubing nearby for prompt response if an adverse event (AE) occurs.

INDICATIONS

Indicated for Use in Hemophilia A and B patients (including acquired Hemophilia A) with inhibitors for:

- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children older than 6 years of age
- The control of spontaneous bleeding episodes
- Surgical interventions

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ADVERSE EFFECTS

Serious thrombotic adverse reactions have been reported when an average cumulative amount of >100 Unit/kg/24 hours of Feiba NF (activated prothrombin complex concentrate [aPCC]) was administered for 24 hours or more to patients receiving Hemlibra prophylaxis. Discontinue Feiba at least 24 hours before starting Hemlibra and avoid use during Hemlibra treatment unless no other treatment options/alternatives are available.

Allergic-type hypersensitivity reactions including anaphylaxis have been reported and are rare and have manifested as pruritus, rash, urticaria, local site reactions, hives, facial swelling, dizziness, hypotension, nausea, chest discomfort, cough, dyspnea, wheezing, flushing, discomfort (generalized) and fatigue.

If an AE is suspected: stop the infusion, and consult the authorized prescriber (AP) for medical management. Notify the TM lab of a suspected reaction.

- Review the product lot number, TM tag and patient ID to rule out a verification (clerical) error and that the expiry date and time has not passed.
- Resume infusion cautiously as directed by AP. Directly observe patient x5min then closely observe x10min.
- Ensure TM tag, along with a copy of the documented clinical data and interventions are sent to TM lab once infusion is discontinued or completed.

DOSAGE

Consult the Bleeding Disorders Clinic or the Hematologist on call for appropriate dosing prior to initial dose:

Ask patient if they have a Factor First card supplying the recommended treatment and dosage

(Adult) Hereditary Bleeding Disorder Clinic 902-473-5612. After hours call 902-473-2220.
(Pediatric) IWK Bleeding Disorder Clinic 902-470-8752. After hours call 1-888-470-8888.
Ask patient if they have a Factor First card supplying the recommended treatment and dosage

For patient specific dosing at the IWK, please see Complex Care Management Plan in the "Alerts" section under "Scanned Permanent Health Records" in the IWK MEDITECH MAGIC system.

COMPATIBILITY, STABILITY

- Compatible with NS
- Draw up reconstituted product with a sterile plastic luer-lock syringe for administration
- Single use vials. Do not use past expiry date
- Do not dilute in any IV solutions
- Prior to reconstitution, vials should be stored in their supplied box to protect from light
- Do not store unused vials in refrigerator. Administer at room temperature

DOSAGE FORMS

- Supplied by Transfusion Medicine (Blood Bank)

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MISCELLANEOUS

- None

RECONSTITUTION

Nominal Strength	Colour Code	Factor VIII Potency Range	Sterile Water Volume
500 units	Orange	350-650 units per vial	10 mL
500 units	Blue	350-650 units per vial	20 mL
1000 units	Light Green	700-1300 units per vial	20 mL
2500 units	Burgundy	1750-3250 units per vial	50 mL

Instructions for use for BAXJECT II Hi-Flow:

Use aseptic technique throughout entire procedure. Don clean gloves.

1. Warm the unopened vial containing the solvent (Sterile Water for Injection, EP) to room temperature if necessary, e.g. using a sterile water bath for warming within several minutes (max. +37°C).

2. Remove the protective caps from the FEIBA vial and solvent vial and cleanse the rubber stoppers with germicidal solution of both and allow to dry. Place the vials on a flat surface.

3. Open the package of BAXJECT II Hi-Flow device by peeling away the paper lid without touching the inside. Do not remove the transfer device from the package.

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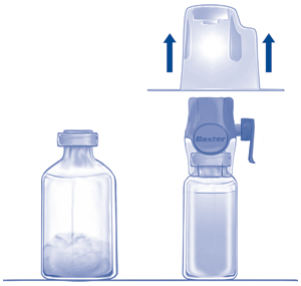
4. Turn the package over and insert the clear plastic spike through the solvent stopper.

5. Grip the package at its edge and pull the package off BAXJECT II Hi-Flow. Do not remove the blue cap from BAXJECT II Hi-Flow.



6. With the transfer device attached to the solvent vial, invert the system so that the solvent vial is on top of the device. Insert the purple plastic spike of BAXJECT II Hi-Flow through the FEIBA vial stopper. The vacuum will draw the solvent into the FEIBA vial.

7. Swirl gently until all the material is dissolved. **Ensure that FEIBA is completely dissolved, otherwise active material will not pass through the device filter.**

Injection

1. Remove the blue cap from BAXJECT II Hi-Flow. Take the syringe and connect it to BAXJECT II Hi-Flow (DO NOT DRAW AIR INTO THE SYRINGE) (Fig. e).

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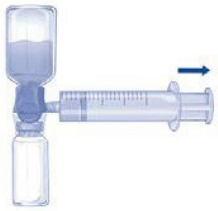
2. Invert the system (with FEIBA vial on top). Draw the FEIBA solution into the syringe by pulling the plunger back slowly (Fig. f).



3. Disconnect the syringe and slowly inject the solution intravenously.

REFERENCES

- CL-BP-030, IWK-625 Blood Component and Blood Product Administration – Policy and Procedure
- Feiba NF product monograph. Found at https://www.takeda.com/en-ca/what-we-do/our-medicines/