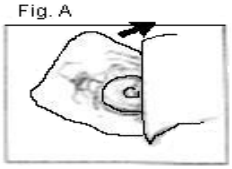
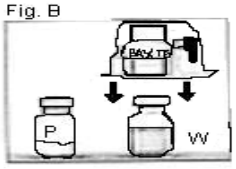
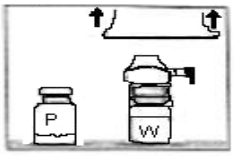
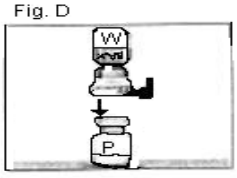
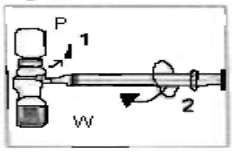
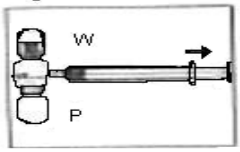
Other Names	• Anti-Inhibitor Coagulant Complex • FEIBA NF
Description	• Freeze dried sterile human plasma fraction with Factor VIII inhibitor bypassing activity. • FEIBA NF shortens the activated partial thromboplastin time (APTT). • FEIBA NF contains Factors II, IX, X mainly non-activated and Factor VII mainly in the activated form. • The product contains approximately equal unitages of Factor VIII inhibitor bypassing activity and Prothrombin Complex factors. • FEIBA NF has been prepared from Source Plasma and/or Fresh Frozen Plasma.

Special Approvals/Authorizations	• An independent 2 person check is required for all doses. Nurses from the Manitoba Bleeding Disorder Program are exempt from the independent 2 person check.
	• A nurse may administer a dose that provides:
	  ○ Up to 200 units greater than the prescribed dose; or
	  ○ No more than 100 units less than the prescribed dose without receiving a new medication order.
	• Patients accustomed to self-administering Factor VIII may continue to do so on the written order of a hematologist or designate.

Classification	**Special Populations:** **Pediatrics (less than 12 years of age):** Case reports and limited clinical trial data suggest that FEIBA can be used in children younger than 6 years for the control of spontaneous bleeding episodes and surgical interventions. No data are available for routine prophylaxis in children younger than 6 years. **Geriatrics (greater than 65 years of age):** No specific data is available on the use of FEIBA in the geriatric population. **Pregnant and nursing women:** The safety of FEIBA NF during pregnancy and lactation has not been established. FEIBA NF should be given to pregnant woman only if clearly needed.

Indications	• For use in Hemophilia A and B patients with inhibitors for:
	  ○ Control of spontaneous bleeding episodes
	  ○ Surgical interventions
	  ○ Routine prophylaxis to prevent or reduce the frequency of bleeding episode in adults and children older than 6 years of age
	• Non-haemophilias with acquired inhibitors to factors VIII, XI, and XII

Contraindications	• Contraindicated in patients known to have normal coagulation mechanism and in patients who have hypersensitivity to the product. • It should not be given to patients with significant signs of disseminated intravascular coagulation (DIC) or fibrinolysis. In patients with tentative or definite diagnosis of coronary heart disease as well as in patients with acute thrombosis and or embolism (including myocardial infarction). The use of FEIBA NF is only indicated in life-threatening bleeding events. **WARNINGS:** • Thromboembolic events have been reported during post-marketing surveillance following infusion of FEIBA, particularly following the administration of high doses and or in patients with thrombotic risk factors.
Supplied	Freeze-Dried Powder, 400-1200 Units per 20 mL, 1750-3250 Units per 50 mL Hemostatic

Dosage	**Treatment Joint Hemorrhage**: 50-75 international units/kg **Treatment Mucous Membrane Bleeding:** 50 international units/kg **Treatment Soft Tissue Hemorrhage (retroperitoneal bleeding)**: 100 international units/kg **Treatment Severe Hemorrhage (CNS bleeding)**: 100 international units/kg **Surgery:** 50-100 international units/kg at 6 hour intervals are recommended. **Routine prophylaxis:** 85±15 international units/kg every other day, 3-4 times weekly**.** **Maximum daily dose of 200 international units/kg should not be exceeded.**
Reconstitution/Stability	**Reconstitution:** FEIBA NF should be reconstituted only with the diluent syringe provided in the FEIBA NF package. Use aseptic technique throughout. 1. Warm the unopened vial containing the solvent (Sterile Water of Injection) to room temperature. 2. Remove the protective caps from the FEIBA vial and solvent vial and cleanse the rubber stoppers with germicidal solution. Place the vials on a flat surface. 3. Open the package of BAXJECT II Hi-Flow device by pealing away the paper lid without touching the inside (Fig. A). Do not remove the transfer device from the package. 4. Turn the package over and insert the clear plastic spike through the solvent stopper (Fig. B). Grip the package at its edge and pull the package off BAXJECT II Hi-Flow (Fig.C). Do not remove the blue cap from BAXJECT II Hi-Flow. 5. 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 (Fig.D). 6. Swirl gently until all the material is dissolved. Ensure that FEIBA is completely dissolved, otherwise active material will not pass through the device filter. 7. 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). 8. Invert the system (with FEIBA vial on top). Draw the FEIBA solution into the syringe by pulling the plunger back slowly (Fig. F). 9. Disconnect the syringe. Slowly inject the solution. Fig. A  Fig. B  Fig. C  Fig. D  Fig. E  Fig. F  W- Water P- Product

	Stability: • Can be stored refrigerated or at room temperature (between 2-25 ^{o}C) for the entire shelf-life of the product. • After reconstitution the solution should be used promptly and must be completed within three hours following reconstitution. • Do NOT administer concurrently with any other product.
Compatibilities/ Incompatibilities	• Should not be mixed with other medicinal products. • Advisable to flush venous access lines with isotonic saline prior to and after infusion of FEIBA.
Administration, Identification and ABO Compatibility	Refer to **Manitoba Best Practice Guidelines** • section 2.2 Standards- Identification and Administration • ABO Compatibility not applicable
Administration, Method	Maximum Concentration: • Not applicable Maximum Rate: • Do not exceed an infusion rate of 2 units FEIBA/kg/body weight per minute. Example: A 15 kg toddler with a diagnosed inhibitor to factor VIII. Physicians order is for 70-80 units/kg or 1050-1200 units. The product is supplied to you as 1 vial of 1103 units in 20 mL. Rate cannot exceed 2 units/kg /minute or 2 units/15 kg/minute = 30 units/minute. Minimum infusion time for this patient is 1103÷30 = 36.7 minutes. To calculate rate for infusion: 20 mL (volume to be absorbed) X 60 (minutes) = 32.67 mL/hour 36.7 (minimum number of minutes for infusion)
Adverse Events	• The most common adverse drug reactions observed were malaise (general discomfort) and arthalgia (joint pain) in a few people. • One subject was withdrawn from study due to an adverse drug reaction of rash. • In the clinical trials there were no reports of any anaphylactic reactions or inhibitor formation. **ADVERSE REACTIONS REPORTED:** GENERAL DISORDERS Malaise, feeling hot, injection site pain NERVOUS SYSTEM DISORDERS Paresthesia, Thrombotic and Embolic stroke IMMUNE SYSTEM DISORDERS Anaphylactic reaction VASCULAR DISORDERS Thrombosis, Venous thrombosis, Arterial thrombosis, Hypertension, Flushing CARDIAC DISORDERS Myocardial infarction, Tachycardia RESPIRATORY DISORDERS Pulmonary embolism, Broncospasm, Wheezing, Cough SKIN DISORDERS Angioedema, Urticaria, Pruritus GASTROINTESTINAL DISORDERS Vomiting, Diarrhea, Abdominal discomfort BLOOD AND LYMPHATIC SYSTEM DISORDERS Disseminated intravascular coagulation (DIC)
References:	FEIBA NF Product Monograph – Date of Approval: September 30, 2014
Reviewed By:	Dr. Donald Houston Dr. Jayson Stoffman