

Instructions for Physician

1. Patients are eligible for fifteen (15) doses in the FEIBA [Anti-Inhibitor Coagulant Complex] FREEDOM OF CHOICE trial program.
2. This prescription will be filled and shipped via overnight courier directly to the patient's address of choice (no PO boxes, please).
3. Complete this enrollment form with patient and prescriber information.
4. Sign the authorization and release below.
5. Fax completed form to **1-866-467-7740**.

- Ship to:
- Healthcare Provider Address*
 - Patient Address

*When shipping to healthcare provider, trial product may only be shipped to prescribing physician.

Patient Information

Patient First Name	Patient Last Name	/	/	Date of Birth (MM/DD/YYYY)
Parent/Guardian First Name (if applicable)	Parent/Guardian Last Name (if applicable)			
Address (where product will be received; no PO boxes)	City	State	ZIP	
Email Address	Phone Number			
Diagnosis				
Allergies: <input type="checkbox"/> None <input type="checkbox"/> Aspirin <input type="checkbox"/> Codeine <input type="checkbox"/> Sulfa <input type="checkbox"/> Other: _____		Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female		<input type="checkbox"/> Select for Spanish-speaking patient

Prescriber Information

Healthcare Provider Name	Facility Name			
License Number (required by law)	Tax ID Number			
Address	City	State	ZIP	
Phone Number	Fax Number			

Prescription Information

Patient Weight	kg	lb		
Total FEIBA units required for one dose (FEIBA vial potency will be determined by the fulfilling pharmacy. Patient will receive enough vials to equal fifteen [15] doses).				
Special dosing instructions (Authorized refills=0. The prescription is valid for one time only with no refills. The patient must obtain a refill prescription of FEIBA for future use).				

Program Terms and Eligibility

- The FREEDOM OF CHOICE Trial Program for FEIBA provides, at no-cost, patients with fifteen (15) trial doses of FEIBA.
- To be eligible: 1) patient must have an ICD-9 or ICD-10 verified diagnosis of hemophilia A or B with inhibitors; and 2) be a new patient not currently using FEIBA and who has not previously enrolled in the FREEDOM OF CHOICE Trial Program for FEIBA.
- These trial doses cannot be exported or transferred in exchange for money, other property, or services. No portion of these trial doses can be used for reimbursement purposes from Medicare, Medicaid, or any other third-party program, which provides cost- or charge-based reimbursement to the participating institution, either directly or indirectly.
- The trial offer prescription is valid for patients not currently using FEIBA. This offer is valid one time only for each patient, with no refills. The patient must obtain a refill prescription for FEIBA for future use.
- This program is valid only for residents of the United States.
- Takeda reserves the right to change or discontinue this program at any time without notice.
- This is not a financial assistance or cost-savings program.

Physician/Prescriber Authorization and Release

I hereby authorize the agents of Takeda to use the above information to process FEIBA trial doses provided free of charge to the above patient. I have obtained consent from this patient to release this information to the mail order pharmacy and the program call center (the agents). I understand that the agents of Takeda will keep this information confidential and will use it only for the FREEDOM OF CHOICE trial program for FEIBA. This usage might include a follow-up survey about the patient's experience and my experience with FREEDOM OF CHOICE. These samples will not be exported or transferred in exchange for money, other property, or services. No portion of these samples will be used for reimbursement purposes, including from Medicare, Medicaid, or any other third-party program, which provides cost- or charge-based reimbursement to the participating institution, either directly or indirectly.

	/	/
Healthcare Provider Signature (no stamps accepted)	Date	

Please see FEIBA Indications and Detailed Important Risk Information on [page 2](#). Please [click here](#) for FEIBA full Prescribing Information, including BOXED WARNING on Embolic and Thrombotic Events.



Indications for FEIBA

FEIBA is an Anti-Inhibitor Coagulant Complex indicated for use in hemophilia A and B patients with inhibitors for:

- Control and prevention of bleeding episodes
- Perioperative management
- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes.

FEIBA is not indicated for the treatment of bleeding episodes resulting from coagulation factor deficiencies in the absence of inhibitors to coagulation factor VIII or coagulation factor IX.

Detailed Important Risk Information for FEIBA

WARNING: EMBOLIC AND THROMBOTIC EVENTS

- **Thromboembolic events have been reported during post-marketing surveillance following infusion of FEIBA, particularly following the administration of high doses (above 200 units per kg per day) and/or in patients with thrombotic risk factors.**
- **Monitor patients receiving FEIBA for signs and symptoms of thromboembolic events.**

CONTRAINDICATIONS

FEIBA is contraindicated in patients with:

- History of anaphylactic or severe hypersensitivity reactions to FEIBA or any of its components, including factors of the kinin generating system
- Disseminated intravascular coagulation (DIC)
- Acute thrombosis or embolism (including myocardial infarction)

WARNINGS AND PRECAUTIONS

Thromboembolic events (including venous thrombosis, pulmonary embolism, myocardial infarction, and stroke) can occur, particularly following the administration of high doses (>200 units/kg/day) and/or in patients with thrombotic risk factors.

Patients with DIC, advanced atherosclerotic disease, crush injury, septicemia, or concomitant treatment with recombinant factor VIIa have an increased risk of developing thrombotic events due to circulating tissue factor or predisposing coagulopathy. Potential benefit of treatment should be weighed against potential risk of these thromboembolic events.

Infusion should not exceed a single dose of 100 units/kg and daily doses of 200 units/kg. Maximum injection or infusion rate must not exceed 2 units/kg/minute. Monitor patients receiving >100 units/kg for the development of DIC, acute coronary ischemia and signs and symptoms of other thromboembolic events. If clinical signs or symptoms occur, such as chest pain or pressure, shortness of breath, altered consciousness, vision, or speech, limb or abdomen swelling and/or pain, discontinue FEIBA and initiate appropriate diagnostic and therapeutic measures.

WARNINGS AND PRECAUTIONS (continued)

Safety and efficacy of FEIBA for breakthrough bleeding in patients receiving emicizumab has not been established. Cases of thrombotic microangiopathy (TMA) were reported in a clinical trial where subjects received FEIBA as part of a treatment regimen for breakthrough bleeding following emicizumab treatment. Consider the benefits and risks with FEIBA if considered required for patients receiving emicizumab prophylaxis. If treatment with FEIBA is required for patients receiving emicizumab, the hemophilia treating physician should closely monitor for signs and symptoms of TMA. In FEIBA clinical studies TMA has not been reported.

Hypersensitivity and allergic reactions, including severe anaphylactoid reactions, can occur. Symptoms include urticaria, angioedema, gastrointestinal manifestations, bronchospasm, and hypotension. Reactions can be severe and systemic (e.g., anaphylaxis with urticaria and angioedema, bronchospasm, and circulatory shock). Other infusion reactions, such as chills, pyrexia, and hypertension have also been reported. If signs and symptoms of severe allergic reactions occur, immediately discontinue FEIBA and provide appropriate supportive care.

Because FEIBA is made from human plasma it may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

FEIBA contains blood group isohemagglutinins (anti-A and anti-B). Passive transmission of antibodies to erythrocyte antigens, e.g., A, B, D, may interfere with some serological tests for red cell antibodies, such as antiglobulin test (Coombs test).

ADVERSE REACTIONS

Most frequently reported adverse reactions observed in >5% of subjects in the prophylaxis trial were anemia, diarrhea, hemarthrosis, hepatitis B surface antibody positive, nausea, and vomiting.

Serious adverse reactions seen are hypersensitivity reactions and thromboembolic events, including stroke, pulmonary embolism and deep vein thrombosis.

DRUG INTERACTIONS

Consider possibility of thrombotic events when systemic antifibrinolytics such as tranexamic acid and aminocaproic acid are used with FEIBA. No adequate and well-controlled studies of combined or sequential use of FEIBA and recombinant factor VIIa, antifibrinolytics, or emicizumab, have been conducted. Use of antifibrinolytics within approximately 6 to 12 hours after FEIBA is not recommended.

Clinical experience from an emicizumab clinical trial suggests that a potential drug interaction may exist with emicizumab.

Please [click here](#) for FEIBA full Prescribing Information, including **BOXED WARNING on Embolic and Thrombotic Events**.