FEIBA [anti-inhibitor coagulant complex]

FREEDOM OF CHOICE™

FEIBA® Trial Program Enrollment Form

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 provider 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 P.O. boxes) | City | State | ZIP

Email Address | Phone Number

Diagnosis

Allergies: ☐ None ☐ Aspirin ☐ Codeine ☐ Sulfa ☐ Other: _____ Gender: ☐ Male ☐ Female ☐ 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

kg lb

Patient Weight

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.
- Shire 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 Shire US Inc. 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 Shire US Inc. 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 the FEIBA Indications and Detailed Important Risk Information including BOXED WARNING on Thromboembolic Events on page 2.
Please click here for FEIBA full Prescribing Information.

Shire

FEIBA [anti-inhibitor coagulant complex]

FREEDOM OF CHOICE™

FEIBA® Trial Program Enrollment Form

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: THROMBOEMBOLIC 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

The use of 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 with FEIBA, particularly following the administration of high doses (above 200 units per kg per day) and/or in patients with thrombotic risk factors.

Thrombotic microangiopathy (TMA) has not been reported in FEIBA clinical studies. Cases of TMAs were reported in an emicizumab clinical trial where subjects received FEIBA as part of a treatment regimen for breakthrough bleeding. The safety and efficacy of FEIBA for breakthrough bleeding in patients receiving emicizumab has not been established. If treatment with FEIBA is considered required for patients receiving emicizumab, patients must be closely monitored by their physicians.

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 with FEIBA should be weighed against the potential risk of these thromboembolic events.

Infusion of FEIBA should not exceed a single dose of 100 units per kg body weight and daily doses of 200 units per kg body weight. Maximum injection or infusion rate must not exceed 2 units per kg of body weight per minute. Monitor patients receiving more than 100 units per kg of body weight of FEIBA 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 the infusion and initiate appropriate diagnostic and therapeutic measures.

Hypersensitivity and allergic reactions, including severe anaphylactoid reactions, can occur following the infusion of FEIBA. The symptoms include urticaria, angioedema, gastrointestinal manifestations, bronchospasm, and hypotension. These 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 administration of 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

The 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.

The serious adverse reactions seen with FEIBA are hypersensitivity reactions and thromboembolic events, including stroke, pulmonary embolism and deep vein thrombosis.

DRUG INTERACTIONS

Consider the possibility of thrombotic events when systemic antifibrinolytics such as tranexamic acid and aminocaproic acid are used during treatment with FEIBA. No adequate and well-controlled studies of the 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 the administration of FEIBA is not recommended.

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

Please see FEIBA full Prescribing Information, including BOXED WARNING on Thromboembolic Events

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