FREEDOM OF CHOICE™
Free Trial Program Enrollment Form

Patients may be eligible to receive 15 free trial doses of FEIBA®

FEIBA [anti-inhibitor coagulant complex]

Fax document to: **1-866-467-7740**

Instructions

1. Review Program Terms and confirm Eligibility criteria below.
2. Healthcare prescriber and patient to complete the enrollment form.
3. Healthcare prescriber and patient to sign the authorization and release. If patient is unable to sign this form prior to submission, Takeda will contact patient to obtain signature.
4. Fax completed form to Takeda at **1-866-467-7740**.
5. Takeda will contact healthcare prescriber or patient to coordinate shipment of trial doses.

PATIENT INFORMATION

Patient Name _____ ☐ ☐

Date of Birth (MM/DD/YYYY) _____ I certify I am new to FEIBA

Gender M F

Address _____ Apt/Unit # _____

City _____ State _____ ZIP _____ Telephone _____ ☐

E-mail _____ Primary Language _____

Patient Guardian Name (if applicable) _____

Address _____ Apt/Unit # _____

City _____ State _____ ZIP _____ Telephone _____

E-mail _____ Primary Language _____

PATIENT AUTHORIZATION AND RELEASE

If patient is unable to sign this form prior to submission, Takeda will contact patient to obtain signature. I authorize any health plan, physician, healthcare professional, hospital, clinic, pharmacy provider, or other healthcare provider (collectively, "Providers") to disclose my (or Patient's) protected health information, including personal information relating to my medical condition, treatment, care management, and health insurance, as well as all information provided on this form and any prescription ("Information"), to Takeda Pharmaceutical Company Limited ("Takeda"). I understand Takeda may provide this Information to its affiliates and their representatives, agents, and contractors, as well as to a specialty pharmacy, for the purpose of facilitating my (or Patient's) participation in the FREEDOM OF CHOICE free trial program. This Information may also be used for internal uses by Takeda, including data analysis.

Patient Signature _____ **Date** _____

Patient Guardian Signature (if applicable) _____ **Date** _____

PATIENT CONSENT FOR FUTURE INFORMATION (OPTIONAL)

☐ By checking this box, I authorize the use of my Information for Takeda marketing activities and consent to receiving marketing and promotional communications from Takeda. I hereby give consent to Takeda, its affiliates, and their agents and representatives to send communications and information to me via the contact information I have provided to Takeda. I understand that this consent will be in effect until such time as I cancel such authorization.

Please see FEIBA Indications and Detailed Important Risk Information on page 4.
Please click here for FEIBA full Prescribing Information, including BOXED WARNING on Embolic and Thrombotic Events.

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SHIPPING

Ship to ☐ Prescriber's office ☐ Patient's home (no PO boxes) **When shipping to prescriber's office, product(s) must be addressed to prescriber.**

Complete this section only if the shipping address differs from the one provided in the "Patient" or "Prescriber" section above.

Name _____ Address _____ Apt/Unit # _____

City _____ State _____ ZIP _____ Telephone _____

E-mail _____

The shipment will include 15 doses of FEIBA. Each dose of FEIBA is packaged with one 10 mL vial of Sterile Water for Injection, one BAXJECT II Hi-Flow Needle-less Transfer Device, and one Package Insert.

PRESCRIBER INFORMATION

The following sections must be completed by the prescriber. Be sure to print all information, and sign before submitting.

Prescriber Name _____ Specialty _____

Facility or Prescriber's Tax ID # _____ NPI # _____

Institution Name _____ Office Contact _____

Office Address _____ Unit # _____

City _____ State _____ ZIP _____

Direct Office Telephone _____ E-mail _____

ICD-10 Diagnosis Code _____

Severity: ☐ Mild ☐ Moderate ☐ Severe Patient's Current Hemophilia A or B with Inhibitors Treatment _____

Your Takeda Representative _____

Please fill out the prescription information below for FEIBA, to be provided as a part of this FREEDOM OF CHOICE program.

Ensure all dosing requirements are included.

Patient Name _____

Address _____ Date of Birth (MM/DD/YYYY) _____

Any Known Allergies _____

Patient Weight (kg) _____

FEIBA Dosage _____

PRESCRIBER AUTHORIZATION AND RELEASE (REQUIRED)

By signing this form, I certify that therapy with FEIBA (as selected above) is medically necessary for the patient identified in this enrollment form ("Patient"). I have reviewed the current FEIBA Prescribing Information and will be supervising Patient's treatment. I have received from Patient, or his/her personal representative, the necessary authorization to release, in accordance with applicable federal and state law regulations, referenced medical and/or other patient information relating to FEIBA therapy to Takeda Pharmaceutical Company Limited, including its agents, representatives, or contractors (collectively, "Takeda"), and to the specialty pharmacy, for the purposes of enrolling the patient in the FREEDOM OF CHOICE free trial program ("Program").

I certify that free trial product provided through the Program will not be exported or transferred in exchange for money, other property, or services. I further certify that no portion of the free trial will be used for reimbursement purposes, including from Medicare, Medicaid, or any third-party program that provides cost- or charge-based reimbursement to the participating institution, either directly or indirectly.

Prescriber Signature _____ **Date** _____

For more information, call Takeda at 1-888-229-8379.

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Program Terms and Eligibility

To be eligible, patients must have a valid prescription and confirmed diagnosis of hemophilia A or B with inhibitors.

TERMS AND CONDITIONS:

1. This free trial offer is solely intended to allow new patients to try FEIBA® [Anti-Inhibitor Coagulant Complex] if clinically necessary, and to determine with their healthcare provider whether FEIBA is right for them. There is no obligation to continue use of FEIBA after the free trial has been completed.
2. This free trial prescription is valid for one time only with no refills. For any future use, the patient must obtain a new prescription for FEIBA.
3. Free trial of FEIBA may only be delivered to the patient's home or to the prescriber's address listed on this enrollment form (no PO boxes).
4. Free trial of FEIBA cannot be exported or transferred in exchange for money, other property, or services.
5. No portion of this free trial may be submitted for reimbursement to any third-party payer, including Medicare or Medicaid, either directly or indirectly.
6. This program is valid only for residents of the United States.
7. Takeda reserves the right to change or discontinue this program at any time without notice.
8. This is not a financial assistance or cost-savings program.
9. Initiation of this free trial program requires certain processing time. It is not intended to provide product(s) to address an active or ongoing bleed at the time of enrollment.

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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.

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