Anti-Inhibitor Coagulant Complex, Steam Treated-EP 500U, FEIBA® STIM 4

ABBREVIATED PRESCRIBING INFORMATION

Before prescribing and for complete details please consult the India Package Insert.

Composition: Active ingredient is Factor VIII Inhibitor Bypassing Activity. 1 ml contains 50 U factor VIII inhibitor bypassing activity. 1 vial FEIBA® 50 U/ml contains 500 U factor VIII inhibitor bypassing activity in 200 – 600 mg human plasma protein. FEIBA® also contains factors II, IX and X, mainly in non-activated form and activated factor VII as well as factor VIII coagulation antigen at a concentration of 0.1 U/1U. **Indication:** Treatment of bleeding in hemophilia A patients with inhibitors. Treatment of bleeding in hemophilia B patients with inhibitors, if no other specific treatment is available. Treatment of bleeding in non-hemophiliacs with acquired inhibitors to factor VIII. Prophylaxis of bleeding in hemophilia A patients with inhibitors who have experienced a significant bleed or are at high risk of significant bleeding. **Posology and method of administration**: Dosage and duration of treatment depend on the severity of the haemostatic disorder, the localization and the extent of the bleeding, as well as the clinical condition of the patient. Dosage and frequency of administration should always be guided by the clinical efficacy in each individual case. As a general guideline, a dose of 50 – 100 U FEIBA® per kg body weight is recommended; a single dose of 100 U/kg body weight and a maximum daily dose of 200 U/kg body weight must not be exceeded unless the severity of bleeding warrants and justifies the use of higher doses. **Contraindications:** FEIBA® must not be used in case of hypersensitivity to the product or any of the components, disseminated intravascular coagulation (DIC) and acute thrombosis or embolism (including myocardial infarction), if therapeutic alternatives to FEIBA® are available. **Warnings and Precautions:** Hypersensitivity Reactions, thrombotic and thromboembolic events. **Interactions**: No adequate studies have been conducted. Consider risk of thromboembolic events if systemic anti-fibrinolytics are used in combination with FEIBA® – use at least 6-12 hours apart. In cases of concomitant rFVIIa use a potential drug interaction cannot be excluded according to available in vitro data and clinical observations (potentially resulting in adverse events such as a thromboembolic event).Clinical experience from an emicizumab clinical trial suggests that a potential drug interaction may exist with emicizumab when FEIBA® was used as part of a treatment regimen for breakthrough bleeding which may result in thromboembolic events and thrombotic microangiopathy Fertility, **Pregnancy and Lactation:** FEIBA® should be prescribed only if clearly needed, taking into consideration that pregnancy and the postpartum period confer an increased risk of thromboembolic events, and several complications of pregnancy that are associated with an increased risk of DIC. **Undesirable Effects:** Common: Hypersensitivity reactions, headache, dizziness, hypotension, rash, hepatitis B surface antibody positive. Unknown frequency: disseminated intravascular coagulation (DIC), increase of inhibitor titre (anamnestic response), anaphylactic reactions, urticaria, paresthesia, hypaesthesia, thrombotic/embolic stroke, somnolence, dysgeusia, cardiac infarction, tachycardia, venous/ arterial thrombosis, embolism (thromboembolic complications), hypertension, flushing, pulmonary embolism, bronchospasm, wheezing, cough, dyspnea, vomiting, diarrhoea, abdominal discomfort, nausea, sensation of numbness in face, angioedema, pruritus, pain at injection site, malaise, feeling hot, chills, pyrexia, chest pain/discomfort. **Overdosage:** High doses may lead to DIC, myocardial infarction or venous thrombosis, and pulmonary embolism. Some of the reported thromboembolic events occurred with doses above 200 U/kg or with patients with other risk factors for thromboembolic events. If signs or symptoms of thrombotic and thromboembolic events are

observed, the infusion should be stopped immediately and appropriate diagnostic and therapeutic measures initiated.

Please refer to the complete package insert for further information.

Manufactured by:
Takeda Manufacturing Austria AG, Industriestrasse 67,1221 Vienna, Austria

Name and Address of Imported and Marketed by:
Takeda Biopharmaceuticals India Pvt. Ltd,
Khasra No. 1/24, 25, 3/1/1, Gala No. 1A-1F, 2A-2E,
3B-3E and 4A-4E, Warehouse No. 1, Sector-76,
Hasanpur Darbaripur, Gurugram, Haryana
India-122004

Suspected Adverse Reactions should be reported at: AE.India@takeda.com.
Consumer Care No: 00080 0050 4087

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Further information is available on request.

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