SURgical Interventions With FEIBA [Anti-Inhibitor Coagulant Complex] (SURF) Study

Program Objectives
- Provide key findings from the international registry of hemophilia patients with inhibitory antibodies treated with FEIBA for surgical interventions
- Discuss FEIBA use during major and minor surgery in patients with inhibitors

Program Description
Surgery in patients with congenital hemophilia and high-titer inhibitors against factor (F) VIII or FIX is challenging because of the need to maintain hemostasis. In this program, we will review the perioperative data collected from an international registry of surgical interventions with FEIBA (SURF). Cases from the registry will be presented to illustrate the use of FEIBA for major and minor surgical procedures in patients with inhibitory antibodies.

Please RSVP to this dinner by contacting the Baxalta Acute Care Manager, Joshua Lukefahr, at joshua_lukefahr@baxalta.com or (573) 352-0282 if you would like to attend.

Indications for FEIBA [Anti-Inhibitor Coagulant Complex]
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.

Selected 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 and/or in patients with thrombotic risk factors.
- Monitor patients receiving FEIBA for signs and symptoms of thromboembolic events.

The use of FEIBA is contraindicated in patients with:
- Known 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)

Please see the reverse side for FEIBA Detailed Important Risk Information
Detailed Important Risk Information For FEIBA [Anti-Inhibitor Coagulant Complex]

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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.

Infusion of FEIBA should not exceed a dose of 100 units per kg body weight every 6 hours 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.

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.

Use of antifibrinolytics within approximately 6 to 12 hours after the administration of FEIBA is not recommended.

Please see enclosed FEIBA full Prescribing Information.

References: