

INHIBITOR

SIGHTS CLEARING THE WAY TO MANAGE PATIENTS WITH INHIBITORS

Distinct Bleed Management For Distinct Diseases

Congenital Hemophilia A or B With Inhibitors and Acquired Hemophilia A

- Inhibitors to Factor VIII or Factor IX are considered the most severe treatment-related complication for hemophilia patients¹
- Up to 33% of patients with severe hemophilia A develop inhibitors²
- Acquired hemophilia A is life-threatening and can worsen if there's a delay in diagnosis, which frequently occurs³



Speaker

Tammuela Singleton, MD
Tulane University School
of Medicine



When

Tuesday, April 17, 2018
6:30PM - 8:30PM



Location

Perry's Steakhouse & Grille
114 West 7th Street
Austin, TX 78701

THIS PROGRAM WILL COVER:



Real world patient
case studies



Insights into congenital
hemophilia with
inhibitors and acquired
hemophilia A



Product information for
FEIBA and OBIZUR

REGISTER NOW

To attend this program, please contact **Mindy Gollin**, at **908-309-0990** or register online at:

<http://www.programsvp.com/HEM-274>

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Please see [page 2](#) for Indications and Detailed Important Risk Information for FEIBA [Anti-Inhibitor Coagulant Complex], including **BOXED WARNING** for Thromboembolic Events.

Please see [page 3](#) for Indications and Detailed Important Risk Information for OBIZUR [Antihemophilic Factor (Recombinant), Porcine Sequence].

This is a non-CME event sponsored by Shire. In accordance with state laws, we are prohibited from providing meals and food items to healthcare professionals licensed or practicing in the states of Minnesota and Vermont. Invited participants may not bring guests. Shire will collect and report healthcare professional information concerning meals and other transfers of value pursuant to the Federal Sunshine Act and state laws.





FEIBA [Anti-Inhibitor Coagulant Complex] Important Information

Indications

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

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)

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 click [here](#) for FEIBA full Prescribing Information.

Please see [page 3](#) for Indication and Detailed Important Risk Information for OBIZUR [Antihemophilic Factor (Recombinant), Porcine Sequence].





Obizur

[Antihemophilic Factor (Recombinant), Porcine Sequence]

OBIZUR [Antihemophilic Factor (Recombinant), Porcine Sequence] Important Information

Indication

OBIZUR, Antihemophilic Factor (Recombinant), Porcine Sequence, is a recombinant DNA derived, antihemophilic factor indicated for the treatment of bleeding episodes in adults with acquired hemophilia A.

Limitations of Use:

- Safety and efficacy of OBIZUR has not been established in patients with baseline anti-porcine factor VIII inhibitor titer greater than 20 BU
- OBIZUR is not indicated for the treatment of congenital hemophilia A or von Willebrand disease

Detailed Important Risk Information

CONTRAINDICATIONS

OBIZUR is contraindicated in patients who have had life-threatening hypersensitivity reactions to OBIZUR or its components (including traces of hamster proteins).

WARNINGS and PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions can occur with OBIZUR. OBIZUR contains trace amounts of hamster proteins. Early signs of allergic reactions, which can progress to anaphylaxis, include angioedema, chest-tightness, dyspnea, hypotension, wheezing, urticaria, and pruritus. Immediately discontinue administration and initiate appropriate treatment if allergic or anaphylactic-type reactions occur.

Inhibitory Antibodies

Inhibitory antibodies to OBIZUR have occurred. Monitor patients for the development of antibodies to OBIZUR by appropriate assays. If the plasma factor VIII level fails to increase as expected, or if bleeding is not controlled after OBIZUR administration, suspect the presence of an anti-porcine factor VIII antibody. If such inhibitory antibodies to anti-porcine factor VIII are suspected and there is a lack of clinical response, consider other therapeutic options.

Monitoring Laboratory Tests

- Perform one-stage clotting assay to confirm that adequate factor VIII levels have been achieved and maintained
 - Monitor factor VIII activity 30 minutes and 3 hours after initial dose
 - Monitor factor VIII activity 30 minutes after subsequent doses
- Monitor the development of inhibitory antibodies to OBIZUR. Perform a Nijmegen Bethesda inhibitor assay if expected plasma factor VIII activity levels are not attained or if bleeding is not controlled with the expected dose of OBIZUR. Use Bethesda Units (BU) to report inhibitor levels

ADVERSE REACTIONS

Common adverse reactions observed in greater than 5% of subjects in the clinical trial were development of inhibitors to porcine factor VIII.

Please click [here](#) for OBIZUR full Prescribing Information.

References

1. Srivastava Haemophilia 2013. Guidelines for the management of hemophilia.
2. DiMichele DM. In Schulman S, ed. Treatment of Hemophilia. 4th ed. Quebec, Canada. WFH. 2008.
3. Collins P, Baudo F, Huth-Kuhne A, et al. Consensus recommendations for the diagnosis and treatment of acquired hemophilia A. BMC Res Notes. 2010;3:161.

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