Obizur
[Antihemophilic Factor (Recombinant), Porcine Sequence]

PLEASE JOIN US FOR A **VIRTUAL** PROGRAM FOR:

OBIZUR®: A FIRST-LINE TREATMENT OPTION FOR ACQUIRED HEMOPHILIA A

Program Objectives

- Review the clinical features, diagnosis, and management of acquired hemophilia A (AHA)
- Share the clinical study data (efficacy and safety) supporting the indication of OBIZUR for treatment of bleeding episodes in adults with AHA
- Discuss patient cases in which OBIZUR may be an appropriate treatment option

PRESENTER

Janet Martin, MSN, RN-BC, CPN
Senior Clinical Specialist
Takeda

PROGRAM INFORMATION

Date Thursday, February 4, 2021

Time 5:30 PM ET

Venue

Virtual Webcast
https://takedaspeakerprograms.webex.com/takedaspeakerprograms/j.php?MTID=m444af3ef67fa2389e951bf73a0ee2501

REGISTRATION INFORMATION

RSVP by

Monday, February 1, 2021

Register online at

http://www.programrsvp.com/3084-424

Or please contact your local Takeda representative

Alison Raymond
alison.raymond@takeda.com

Indication

OBIZUR, Antihemophilic Factor (Recombinant), Porcine Sequence, is a recombinant DNA derived, antihemophilic factor indicated for the on-demand treatment and control 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).

Please see OBIZUR Detailed Risk Information on the following page.
Please see accompanying OBIZUR full Prescribing Information.

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

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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, including anamnestic reactions with rise in human FVIII inhibitors and/or porcine FVIII inhibitors, 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 are suspected and there is a lack of clinical response, consider management options such as discontinuing OBIZUR and initiating other therapeutics such as a Factor VIII bypassing agent.

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 see accompanying OBIZUR full Prescribing Information.

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