

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.

For print pieces:

Please see accompanying OBIZUR full Prescribing Information

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