SUGGESTED INFUSION SUPPLY LIST

Fabrazyme® agalsidase beta

General Supplies:
Gloves, Tape, Gauze 2x2, Band-aids, Coban wrap or similar
Blood Pressure Cuff- appropriate for patient (adult vs pediatric cuff size)
Thermometer
Supplies for aseptic preparation (e.g., isopropyl alcohol)
Pre-medications as per physician order (e.g., antipyretics, antihistamines, etc.)
Appropriate medical support measures should be readily available when Fabrazyme is administered
Additional supplies as per institutional protocol (e.g., labels for IV bag)
Sharps container

Preparation and Administration Supplies:
Fabrazyme vials as per prescription and Infusion Orders
Sterile Water for Injection, USP
0.9% Sodium Chloride Injection, USP
Extra 0.9% Sodium Chloride for pre-infusion prime and post infusion flush
Syringes for reconstitution and dilution (e.g., 1 mL, 10 mL, 20 mL, and 60 mL syringes)
Needles (e.g., 18 gauge to 20 gauge needles) – do not use filtered needles
IV start Kit or port access kit – IV catheters – appropriate size for patient
Programmable Pump – Supply batteries/plug in, IV Pole or pack to hold.
Compatible Intravenous administration tubing set for the programable pump
In-line low protein binding filter- 0.2 µm extension set (an additional set may be needed in case filter clogs)

INDICATION AND USAGE
Fabrazyme® is indicated for the treatment of adult and pediatric patients 2 years of age and older with confirmed Fabry disease.

IMPORTANT SAFETY INFORMATION

WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS
Patients treated with enzyme replacement therapies have experienced life-threatening hypersensitivity reactions, including anaphylaxis. Anaphylaxis has occurred during the early course of enzyme replacement therapy and after extended duration of therapy.
Initiate FABRAZYME in a healthcare setting with appropriate medical monitoring and support measures, including access to cardiopulmonary resuscitation equipment. If a severe hypersensitivity reaction (e.g. anaphylaxis) occurs, discontinue FABRAZYME and immediately initiate appropriate medical treatment, including use of epinephrine.
Inform patients of the symptoms of life-threatening hypersensitivity reactions, including anaphylaxis and to seek immediate medical care should symptoms occur *[see Warnings and Precautions (5.1)]*

Please see additional Important Safety Information on the following page and full Prescribing Information.

© 2024 Genzyme Corporation. All rights reserved.
Fabrazyme and Sanofi are registered trademarks of Sanofi or an affiliate. MAT-US-2109106-v3.0-7/2024

IMPORTANT SAFETY INFORMATION

Fabrazyme® agalsidase beta

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions Including Anaphylaxis

In clinical trials and post-marketing experience, approximately 1% of patients developed anaphylactic or severe hypersensitivity reactions, some life-threatening, during Fabrazyme infusion. Reactions have included localized angioedema (including swelling of the face, mouth, and throat), bronchospasm, hypotension, generalized urticaria, dysphagia, rash, dyspnea, flushing, chest discomfort, pruritus, and nasal congestion. Consider pretreating with antihistamines, antipyretics, and/or corticosteroids; however, reactions may still occur.

In Fabrazyme clinical trials, some patients developed IgE antibodies or skin test reactivity specific to Fabrazyme.

- Higher incidences of hypersensitivity reactions were observed in adult patients with persistent anti-Fabrazyme antibodies, and in those with high antibody titers compared with antibody negative adult patients.
- Consider testing for IgE antibodies in patients who experienced suspected hypersensitivity reactions and consider the risks and benefits of continued treatment in patients with anti-Fabrazyme IgE antibodies. Rechallenge of these patients should only occur under the direct supervision of qualified personnel, with appropriate medical support measures readily available.

Infusion-Associated Reactions

In Fabrazyme clinical trials, 59% of patients experienced infusion-associated reactions (IARs), some of which were severe. IARs are defined as those occurring on the same day as the infusion. The incidence of these reactions was higher in patients who were positive for anti-Fabrazyme antibodies than those negative for anti-Fabrazyme antibodies.

- Consider pretreatment with antipyretics, antihistamines, and/or corticosteroids to reduce the risk of IARs; however, they may still occur.
- If a mild or moderate IAR occurs, consider holding the infusion temporarily, decreasing the infusion rate, and/or reducing the Fabrazyme dosage. If a severe IAR occurs, discontinue Fabrazyme immediately and initiate appropriate medical treatment as needed. Assess the risks and benefits of readministering Fabrazyme and monitor patients closely if readministering.
- Patients with advanced Fabry disease may have compromised cardiac function, which may predispose them to a higher risk of severe complications from IARs. Closely monitor patients with compromised cardiac function receiving Fabrazyme

Common Adverse Reactions

Adverse reactions reported (≥20%) were upper respiratory tract infection, chills, pyrexia, headache, cough, paresthesia, fatigue, peripheral edema, dizziness, and rash.

Please see full Prescribing Information. including BOXED warning.

© 2024 Genzyme Corporation. All rights reserved.
Fabrazyme and Sanofi are registered trademarks of Sanofi or an affiliate. MAT-US-2109106-v3.0-7/2024