SUGGESTED INFUSION SUPPLY LIST

As of February 2024

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® (agalsidase beta) is indicated for the treatment of adult and pediatric patients 2 years of age and older with confirmed Fabry disease.

Warnings and Precautions

Anaphylaxis and Hypersensitivity Reactions

In clinical trials and post marketing safety experience with Fabrazyme, approximately 1% of patients developed anaphylactic or severe hypersensitivity reactions during Fabrazyme infusion. Life-threatening anaphylactic and severe hypersensitivity reactions have been observed in patients during Fabrazyme infusions.

- 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.

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

IMPORTANT SAFETY INFORMATION

Fabrazyme® agalsidase beta

Warnings and Precautions

Anaphylaxis and Hypersensitivity Reactions (continued)

- Interventions have included cardiopulmonary resuscitation, oxygen supplementation, IV fluids, hospitalization, and treatment with inhaled beta-adrenergic agonists, antihistamines, epinephrine, and IV corticosteroids.
- If anaphylactic or severe hypersensitivity reactions occur, immediately discontinue administration of Fabrazyme and provide necessary emergency treatment. Because of the potential for severe hypersensitivity reactions, appropriate medical support measures should be readily available when Fabrazyme is administered.

In the clinical studies, some patients developed IgE antibodies or a reaction to an allergy skin test specific to Fabrazyme. IgE antibodies are a specific kind of antibody that can sometimes be produced by the body's immune system during an allergic reaction.

- Higher amounts of hypersensitivity reactions were seen in adult patients whose immune systems repeatedly made anti-Fabrazyme antibodies and in patients who had high antibody titers (units used to measure how much anti-drug-antibody your immune system is making) compared to adult patients with negative antibody titers.
- Your doctor should consider testing for IgE antibodies if you experience suspected allergic reactions. Providing Fabrazyme to patients who have experienced severe or serious allergic reactions to Fabrazyme should only be done after carefully considering the risks and benefits of continuing the treatment, and only under the direct supervision of a qualified healthcare professional and with appropriate medical support readily available.

Infusion-Associated Reactions

In clinical studies with Fabrazyme, 59% of patients experienced infusion-associated reactions during Fabrazyme administration, some of which were severe. Infusion-associated reactions are defined as adverse reactions occurring on the same day as your infusion. During the clinical trials, infusion-associated reactions occurred more frequently in patients who were positive for anti-Fabrazyme antibodies than in patients who did not have anti-Fabrazyme antibodies.

- For patients who have had reactions to their infusions, it is recommended that they be given anti-fever and antihistamine medications right before their next infusions. Infusion-associated reactions have happened in some patients even after taking these medications before their infusions.
- If an infusion-associated reaction occurs, slowing the infusion rate, stopping the infusion for a short time and/or giving more anti-fever and antihistamine medications and or steroids may improve the symptoms.

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IMPORTANT SAFETY INFORMATION

Fabrazyme® agalsidase beta

Warnings and Precautions

Infusion-Associated Reactions (continued)

- If severe infusion-associated reactions happen, your healthcare professional should consider stopping the Fabrazyme infusion right away and should provide medical care for your condition. Severe reactions are generally managed by giving antihistamine medications, corticosteroids, fluids through the vein, and/or oxygen when needed. Because severe infusion-associated reactions may happen, medical treatment should be readily available during your Fabrazyme infusion.
- People with advanced Fabry disease may have heart problems which could put them at a higher risk for severe complications from infusion-associated reactions. These patients should be watched closely during their infusion if the decision is made to give them Fabrazyme.

Common and Other Possible Side Effects: Common side effects reported in 20% or more of Fabrazyme treated patients in clinical studies compared to placebo were upper respiratory tract infection, chills, fever, headache, cough, burning and/or tingling sensation, fatigue, swelling in the legs, dizziness and rash.

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