

Fabrazyme[®] (agalsidase beta) Dosing & Administration



SUPPLIES AND EQUIPMENT:

1. Fabrazyme[®] vials
2. Sterile Water for Injection, USP
3. 500 mL bag/bottle of 0.9% Sodium Chloride Injection, USP
4. Premedication (antipyretics)
5. Syringes for reconstitution and dilution
6. Needles (without filtering devices)
7. Intravenous administration set
8. In-line low protein-binding 0.2 μm filter (optional)
9. Additional supplies as per the institution's IV infusion protocol

Note: Make sure the patient is ready to receive treatment before reconstituting the enzyme.
Fabrazyme[®] vials do not contain preservatives and should not be stored for subsequent use once reconstituted.

PREPARATION:

1. Verify patient dosage (recommended Fabrazyme[®] dosage is 1.0 mg/kg body weight) and remove the appropriate number of Fabrazyme[®] vials from the refrigerator. The number of 35 mg and 5 mg vials needed is based on the patient's body weight and the recommended dose.

To calculate dose:

Patient weight (in kg) = Patient dose (in mg)

- Patient dose (in mg) ÷ 5 mg/mL = number of mL of reconstituted Fabrazyme[®] required for patient dose
- Based on the patient dose in mL, determine the number of 35 mg vials (7 mL extractable volume) and 5 mg vials (1 mL extractable volume) needed.

2. Bring Fabrazyme[®] vials to room temperature (approximately 30 minutes). DO NOT USE Fabrazyme[®] after the expiration date on the vial.
3. Prepare a clean work area and organize necessary supplies and equipment for reconstitution and administration.

RECONSTITUTION AND DILUTION: (using aseptic technique)

1. Remove and discard plastic protective caps from vials. Clean vial tops with an alcohol wipe.
2. Reconstitute each Fabrazyme[®] vial by **slowly** injecting the appropriate amount of Sterile Water for Injection, USP to the inside wall of each vial. 35 mg vials require 7.2 mL and 5 mg vials require 1.1 mL.
3. Roll and tilt each vial gently. Each vial will yield a 5.0 mg/mL clear, colorless solution.
4. Visually inspect the reconstituted vials for particulate matter and discoloration. Do not use the reconstituted solution if there is particulate matter or if it is discolored.
5. The reconstituted solution should be further diluted with 0.9% Sodium Chloride Injection, USP to a final total volume of 500 mL. Prior to adding the volume of reconstituted Fabrazyme[®] required for the patient dose, remove an equal volume of 0.9% Sodium Chloride for Injection, USP from the 500 mL infusion bag. Slowly withdraw the reconstituted solution from each vial up to the total volume required for the patient dose. It is important to inject the reconstituted Fabrazyme[®] solution directly into the Sodium Chloride solution rather than into the air space within the infusion bag. Discard any vial with unused reconstituted solution.
6. Gently invert infusion bag to mix the solution, avoiding vigorous shaking and agitation.
7. Fabrazyme[®] should not be infused in the same intravenous line with other products.
8. The diluted solution may be filtered through an in-line low protein-binding 0.2 μm filter during administration.

ADMINISTRATION:

1. Explain the administration procedure to the patient.
2. Administer antipyretics to the patient prior to infusion (see Warnings section of full prescribing information).
3. Obtain appropriate baseline vital signs prior to the infusion.
4. Obtain IV access. Antecubital, wrist, or hand veins may be used for access.
5. Draw required blood work and flush line with 0.9% Sodium Chloride Injection, USP.
6. Connect the IV tubing to the bag/bottle with Fabrazyme[®].
7. Prime the tubing and expel any air prior to the administration of Fabrazyme[®].
8. Attach IV tubing and begin Fabrazyme[®] infusion.
9. The initial IV rate should be no more than 0.25 mg/min (15 mg/hr). The infusion rate may be slowed in the event of infusion-associated reactions. After patient tolerance to the infusion is well established, the infusion rate may be increased in increments of 0.05 to 0.08 mg/min (in increments of 3 to 5 mg/hr) each subsequent infusion. Thirty-one of 58 (53%) patients have received infusions at rates ≥33 mg/hr.
10. Monitor the patient's vital signs at regular intervals.
11. When the infusion is complete, flush the tubing with 0.9% Sodium Chloride Injection, USP to remove any residual Fabrazyme[®] in the tubing. The flush should be infused.

IMPORTANT POINTS:

1. Follow your institution's policy for IV insertion and medication infusion.
2. Because of the potential for infusion reactions, appropriate medical support measures should be readily available when Fabrazyme[®] is administered.
3. If an infusion reaction occurs, decreasing the infusion rate, temporarily stopping the infusion, and/or administration of additional antipyretics, antihistamines and/or steroids may ameliorate the symptoms.
4. Adverse events should be reported promptly to Genzyme's Medical Information department at 800-745-4447 or 617-768-9000.

Please see full prescribing information.

www.fabrazyme.com

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