Fact Sheet

Fabrazyme®
agalsidase beta

INDICATION AND USAGE

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

DOSAGE

The recommended Fabrazyme dosage is 1 mg/kg body weight infused every two weeks as an intravenous (IV) infusion.

HOW SUPPLIED

Fabrazyme is supplied as a sterile, nonpyrogenic, white to off-white lyophilized cake or powder in single-dose vials for reconstitution of 5 mg or 35 mg.

STORAGE

Refrigerate vials of Fabrazyme at 2˚C to 8˚C (36˚F to 46˚F). Do not use Fabrazyme after the expiration date on the vial.

This product contains no preservatives. Reconstituted and diluted solutions of Fabrazyme should be used immediately. If immediate use is not possible, the reconstituted and diluted solution may be stored for up to 24 hours at 2˚C to 8˚C (36˚F to 46˚F)

GENERAL TERMS & CONDITIONS

Terms: Net 60 days, FOB Destination, Freight Prepaid.

PRICING INFORMATION

Call 1-800-745-4447

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Anaphylaxis and Hypersensitivity Reactions

In clinical trials and postmarketing 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.
- 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 clinical trials with Fabrazyme, 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 adult patients with high antibody titer compared to that in antibody negative adult patients.
- Physicians should 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 clinical trials with Fabrazyme, 59% of patients experienced infusion-associated reactions, some of which were severe. Infusion-associated reactions are defined as adverse reactions occurring on the same day as the infusion. The incidence of infusion-associated reactions was higher in patients who were positive for anti-Fabrazyme antibodies than in patients who were negative for anti-Fabrazyme antibodies.

- In patients experiencing infusion-associated reactions, pretreatment with an antipyretic and antihistamine is recommended. Infusion-associated reactions occurred in some patients after receiving pretreatment.

Please see accompanying full Prescribing Information.

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Fabrazyme® (agalsidase beta)

IMPORTANT SAFETY INFORMATION CONTINUED

- If an infusion-associated reaction occurs, decreasing the infusion rate, temporarily stopping the infusion, and/or administrating additional antipyretics, antihistamines, and/or steroids may ameliorate the symptoms.
- If severe infusion-associated reactions occur, immediate discontinuation of the administration of Fabrazyme should be considered, and appropriate medical treatment should be initiated. Severe reactions are generally managed with administration of antihistamines, corticosteroids, intravenous fluids, and/or oxygen when clinically indicated. Because of the potential for severe infusion-associated reactions, appropriate medical support measures should be readily available when Fabrazyme is administered.
- Patients with advanced Fabry disease may have compromised cardiac function, which may predispose them to a higher risk of severe complications from infusion-associated reactions. Monitor closely patients with compromised cardiac function if Fabrazyme is administered to these patients

ADVERSE REACTIONS

- Common adverse reactions reported (≥20% and >2.5% compared to placebo) were upper respiratory tract infection (53% vs 42%), chills (49% vs 13%), pyrexia (39% vs 22%), headache (39% vs 28%), cough (33% vs 25%), paresthesia (31% vs 18%), fatigue (24% vs 17%), peripheral edema (21% vs 7%), dizziness (21% vs 8%), and rash (20% vs 10%).

SHIPPING AND DELIVERY

Fabrazyme is available directly through Sanofi Genzyme or through its distributors. In many cases, distributors can ship Fabrazyme and then bill the patient's insurance company directly. Sanofi Genzyme's shipping hours are Monday - Friday 8:00 am - 5:00 pm EST. Call Sanofi Genzyme Support Services at 617-768-9000 (option 1) or toll-free 800-745-4447 (option 1) for more information on ordering Fabrazyme.

RETURNED GOODS

Fabrazyme is a non-returnable product, except in cases of Sanofi Genzyme shipping error or product defect. Sanofi Genzyme reserves the right to review other return requests on a case-by-case basis and may subsequently allow returns in its sole discretion.

All returns require prior authorization from Sanofi Genzyme. Call Sanofi Genzyme Product Services at toll-free 800-745-4447 (Option 1) Monday - Friday 8:00 am - 6:00 pm EST for return authorization. Fabrazyme Returned Goods Authorization Policy is available upon request.

ICD-9-CM	272.7 – Lipidosis (Fabry disease)
ICD-10-CM	E75.21 Fabry (Anderson) disease
NDC	58468-0040-1 (35 mg vial) 58468-0041-1 (5 mg vial)
HCPCS	J0180 – Fabrazyme – injection agalsidase beta, 1mg
CPT-4	96365 – Intravenous infusion therapy prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour 96366 – Each additional hour. (List separately in addition to primary procedure code, 96365)
Revenue	260 – General IV therapy service 261 – Infusion pump 258 – IV solutions 636 – Drugs and biologicals requiring a HCPCS code

Note

- Since third party payers evaluate treatment based on medical necessity, expected outcome, and cost, they generally require documentation of diagnosis and clinical symptoms of Fabry disease. This information may need to be submitted with the claim; for specific requirements check with the payer.
- To help avoid potential problems obtaining reimbursement, the treating physician should request written confirmation of coverage from the third party payer prior to initiation of enzyme replacement therapy.

Questions? Contact Sanofi Genzyme Patient and Product Services at 1-800-745-4447 or 1-617-768-9000 (option 3).

PRODUCT INFORMATION

Please see accompanying full Prescribing Information.

NDC 58468-0040-1 (35 mg)
NDC 58468-0041-1 (5 mg)

BILLING CODES

The above codes may be used to communicate services rendered when filing claims for Fabrazyme. These codes are being provided for informational purposes only and should be verified, as codes may change. The provision of billing codes does not constitute reimbursement or legal advice. Providers are solely responsible for ensuring the accuracy of the billing codes submitted to any payer.

Please see accompanying full Prescribing Information.

www.fabrazyme.com

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