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

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)].*

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.

Fabrazyme® (agalsidase beta)

IMPORTANT SAFETY INFORMATION CONTINUED

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.

SHIPPING AND DELIVERY

Fabrazyme is available directly through Sanofi or through its distributors. In many cases, distributors can ship Fabrazyme and then bill the patient's insurance company directly. Sanofi's shipping hours are Monday - Friday 8:00 am - 5:00 pm EST. Call Sanofi 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 shipping error or product defect. Sanofi 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. Call Sanofi 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 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 full Prescribing Information, including Boxed WARNING Boxed Warning
www.fabrazyme.com

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