

Fact Sheet



INDICATIONS AND USAGE

Fabrazyme (agalsidase beta) is indicated for use in patients with Fabry disease. Fabrazyme reduces globotriaosylceramide (GL-3) deposition in capillary endothelium of the kidney and certain other cell types.

The reduction of GL-3 inclusions suggests that Fabrazyme may ameliorate disease expression; however, the relationship of GL-3 inclusion reduction to specific clinical manifestations of Fabry disease has not been established.

DOSAGE

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

HOW SUPPLIED

Fabrazyme is supplied as a sterile, nonpyrogenic, white to off-white lyophilized cake or powder. Fabrazyme 35 mg vials are supplied in single-use, clear Type I glass 20 mL (cc) vials. The closure consists of a siliconized butyl stopper and an aluminum seal with a plastic purple flip-off cap. Fabrazyme 5 mg vials are supplied in single-use, clear Type I glass 5 mL (cc) vials. The closure consists of a siliconized butyl stopper and an aluminum seal with a plastic gray flip-off cap.

STORAGE

Store Fabrazyme vials under refrigeration between 2° to 8°C (36° to 46°F). DO NOT USE Fabrazyme after the expiration date on the vial. Reconstituted and diluted solutions of Fabrazyme should be used immediately. This product contains no preservatives. If immediate use is not possible, the reconstituted and diluted solution may be stored for up to 24 hours at 2° to 8°C (36° to 46°F).

GENERAL TERMS & CONDITIONS

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

PRICING INFORMATION

Call 1-800-745-4447

IMPORTANT SAFETY INFORMATION

Life-threatening anaphylactic and severe allergic reactions have been observed in patients during Fabrazyme infusions. In clinical trials and postmarketing safety experience, approximately 1% of patients developed anaphylactic or severe allergic reactions 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 severe allergic or anaphylactic reactions occur, immediately discontinue administration of Fabrazyme and provide necessary emergency treatment. Because of the potential for severe allergic reactions, appropriate medical support measures should be readily available when Fabrazyme is administered.

In patients experiencing infusion reactions, pretreatment with an antipyretic and antihistamine is recommended. Infusion reactions occurred in some patients after receiving pretreatment with antipyretics, antihistamines, and oral steroids. If an infusion reaction occurs, decreasing the infusion rate, temporarily stopping the infusion, and/or administering additional antipyretics, antihistamines, and/or steroids may ameliorate the symptoms. If severe infusion 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 reactions, appropriate medical support measures should be readily available when Fabrazyme is administered.

Re-administration of Fabrazyme to patients who have previously experienced severe or serious allergic reactions to Fabrazyme should be done only after careful consideration of the risks and benefits of continued treatment, and only under the direct supervision of qualified personnel and with appropriate medical support measures readily available.

The most common adverse reactions reported are infusion reactions, some of which were severe. Infusion reactions occurred in approximately 50-55% of patients during Fabrazyme administration in clinical trials. Serious and/or frequently occurring ($\geq 5\%$ incidence) related adverse reactions consisted of one or more of the following: chills, fever, feeling hot or cold, dyspnea, nausea, flushing, headache, vomiting, paresthesia, fatigue, pruritus, pain in extremity, hypertension, chest pain, throat tightness, abdominal pain, dizziness, tachycardia, nasal congestion, diarrhea, edema peripheral, myalgia, back pain, pallor, bradycardia, urticaria, hypotension, face edema, rash, and somnolence.

Patients with advanced Fabry disease may have compromised cardiac function, which may predispose them to a higher risk of severe complications from infusion reactions. Patients with compromised cardiac function should be monitored closely if the decision is made to administer Fabrazyme.

Other serious adverse events reported in clinical studies included stroke, pain, ataxia, bradycardia, cardiac arrhythmia, cardiac arrest, decreased cardiac output, vertigo, hypoacusia, and nephrotic syndrome. These adverse events also occur as manifestations of Fabry disease; an alteration in frequency or severity cannot be determined from the small numbers of patients studied.

Please see accompanying full Prescribing Information.

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Fabrazyme® (agalsidase beta)

IMPORTANT SAFETY INFORMATION CONTINUED

Severe and serious infusion related reactions have been reported in postmarketing experience, some of which were life threatening including anaphylactic shock. In addition to the above adverse reactions, the following have been reported during postmarketing use of Fabrazyme: arthralgia, asthenia, erythema, hyperhidrosis, infusion site reaction, lacrimation increased, leukocytoclastic vasculitis, lymphadenopathy, hypoesthesia, oral hypoesthesia, palpitations, rhinorrhea, oxygen saturation decreased and hypoxia.

Adverse reactions (regardless of relationship) resulting in death reported in the postmarketing setting with Fabrazyme treatment included cardiorespiratory arrest, respiratory failure, cardiac failure, sepsis, cerebrovascular accident, myocardial infarction, renal failure, and pneumonia. Some of these reactions were reported in Fabry disease patients with significant underlying disease.

The safety and efficacy in patients younger than 8 years of age have not been evaluated.

Most patients who develop IgG antibodies do so within the first three months of exposure. IgG seroconversion in pediatric patients was associated with prolonged half-life of Fabrazyme, a phenomenon rarely observed in adult patients.

In clinical trials, a few patients developed IgE or skin test reactivity specific to Fabrazyme. Physicians should consider testing for IgE in patients who experienced suspected allergic reactions and consider the risks and benefits of continued treatment in patients with anti-Fabrazyme IgE antibodies.

Fabrazyme is available by prescription only. Side effects should be reported promptly to Genzyme Medical Information at 800-745-4447, option 2. To learn more, please see the full prescribing information, visit www.fabrazyme.com, or contact Genzyme at 1-800-745-4447.

SHIPPING AND DELIVERY

Fabrazyme is available directly through Genzyme or through its distributors. In many cases, distributors can ship Fabrazyme and then bill the patient's insurance company directly. Genzyme Therapeutics' shipping hours are Monday - Friday 8:00 am - 5:00 pm EST. Call Genzyme Therapeutics Product 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 Genzyme shipping error or product defect. 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 Genzyme. Call Genzyme Therapeutics 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.

Please see accompanying full Prescribing Information.

www.fabrazyme.com
www.fabryregistry.com

ICD-9-CM	272.7 – Lipidosis (Fabry disease)
NDC	58468-0040-1 (35 mg vial) 58468-0041-1 (5 mg vial)
HCPCS	J0180 – Fabrazyme – injection agalsidase beta, 1 mg
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 or contact Genzyme Patient and Product Services.
- 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. A Case Manager in Genzyme Patient and Product Services can assist in obtaining written authorization for Fabrazyme treatment.

Questions? Contact 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 following codes may be used to communicate services rendered when filing claims for Fabrazyme.

Providers are responsible for the selection of appropriate codes. Information in the table provides a general framework for understanding possible coding alternatives. It should not be used as a substitute for a healthcare professional's own judgment. Any specific guidance or direction regarding claims submission offered by the payer supersedes the information in this guide.

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