



# Fabrazyme®

## agalsidase beta



### INDICATION

Fabrazyme® is indicated for use in patients with Fabry disease. Fabrazyme® reduces globotriaosylceramide (GL-3) deposition in the capillary endothelium of the kidney and certain other cell types. The reduction of GL-3 inclusions suggests 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 1.0 mg/kg body weight infused every 2 weeks as an IV infusion.

### HOW SUPPLIED

Fabrazyme® is supplied as a sterile, nonpyrogenic, white to off-white lyophilized cake or powder product. Fabrazyme® is 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.

### STORAGE

Store Fabrazyme® vials under refrigeration between 2° - 8°C (36° - 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° - 8°C (36° - 46°F).

### GENERAL TERMS & CONDITIONS

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

### PRICING INFORMATION

Genzyme's Manufacturer's Direct Price: \$3,800.00 per 35 mg vial. Please check independent reporting resources such as Redbook and First Databank for current AWP pricing.

The AWP as listed by First Databank and Redbook is \$4,750.00 and \$4,560.00 per 35 mg vial, respectively. Genzyme does not set, sell at, or survey for this price.

### IMPORTANT SAFETY INFORMATION

The most serious and most common adverse reactions reported with Fabrazyme® are infusion reactions. Infusion reactions may include tachycardia, hypertension, throat tightness, chest pain/tightness, dyspnea, fever, chills/rigors, abdominal pain, pruritus, urticaria, nausea, vomiting, lip or ear edema, rash, hypotension, myalgia, and headache. Infusion reactions occurred in many patients treated with Fabrazyme® and some of the reactions were severe. Patients should be given antipyretics prior to infusion. Infusion reactions occurred in some patients after receiving antipyretics, antihistamines, and oral steroids.

Side effects should be reported promptly to Genzyme Medical Information at 800-745-4447. Fabrazyme® is available by prescription only. For more information, please see full prescribing information.

### SHIPPING AND DELIVERY

Fabrazyme® is available directly through Genzyme or through its distributors. Distributors can ship Fabrazyme® and then bill the patient's insurance company directly. Shipping hours are Monday - Friday 8:00 am - 5:00 pm EST. Call Genzyme Therapeutics Product Services at 800-745-4447 or 617-768-9000 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 800-745-4447 (Option#1) Monday - Friday 8:00 am - 6:00 pm EST for return authorization. Fabrazyme® return goods Authorization Policy is available upon request.

### BILLING CODES

The following codes may be used to communicate services rendered when filing claims for Fabrazyme®. Note that any specific guidance or direction on the submission of claims offered by the payer supercede the codes suggested below.

ICD-9-CM	272.7 - Lipidosis (Fabry disease)
NDC	58468-0040-1 - 35 mg
HCPCS	J3490 - agalsidase beta injection, mg/kg dose C9208 - Injection, agalsidase beta, per 1 mg
CPT-4	90780 - IV infusion up to one hour 90781 - Each additional hour, up to eight hours Q0081 - Non-chemotherapeutic infusion (hospital only)
Revenue	260 - General IV therapy service 261 - Infusion pump 258 - IV solutions 636 - Drugs requiring a HCPCS code

[www.fabrazyme.com](http://www.fabrazyme.com)  
[www.fabrycommunity.com](http://www.fabrycommunity.com)  
[www.fabryregistry.com](http://www.fabryregistry.com)

genzyme

### PRODUCT INFORMATION

Please see accompanying full prescribing information.

**NDC 58468-0040-1**