Lumizyme®
(alglucosidase alfa)

Fact Sheet

INDICATION
LUMIZYME®(alglucosidase alfa) is a hydrolytic lysosomal glycogen-specific enzyme indicated for patients with Pompe disease (GAA deficiency).

WARNING: RISK OF ANAPHYLAXIS, HYPERSENSITIVITY AND IMMUNE-MEDIATED REACTIONS, and RISK OF CARDIORESPIRATORY FAILURE

Life-threatening anaphylactic reactions and severe hypersensitivity reactions, presenting as respiratory distress, hypoxia, apnea, dyspnea, bradycardia, tachycardia, bronchospasm, throat tightness, hypotension, angioedema (including tongue or lip swelling, periorbital edema, and face edema), and urticaria, have occurred in some patients during and after alglucosidase alfa infusions. Immune-mediated reactions presenting as proteinuria, nephrotic syndrome, and necrotizing skin lesions have occurred in some patients following alglucosidase alfa treatment. Closely observe patients during and after alglucosidase alfa administration and be prepared to manage anaphylaxis and hypersensitivity reactions. Inform patients of the signs and symptoms of anaphylaxis, hypersensitivity reactions, and immune-mediated-reactions and have them seek immediate medical care should signs and symptoms occur.

Infantile-onset Pompe disease patients with compromised cardiac or respiratory function may be at risk of serious acute exacerbation of their cardiac or respiratory compromise due to fluid overload, and require additional monitoring.

Please see reverse for additional Important Safety Information.

Dosage
The recommended dosage of alglucosidase alfa is 20 mg/kg body weight administered every 2 weeks as an intravenous infusion. The total volume of infusion is determined by the patient's body weight and should be administered over approximately 4 hours.

How Supplied
Lumizyme 50 mg vials are supplied as a sterile, nonpyrogenic, white to off-white lyophilized cake or powder in single-use vials for reconstitution. After reconstitution, the resultant solution concentration is 5 mg/mL.

Storage and Handling
Store Lumizyme under refrigeration between 2°C and 8°C (36°F to 46°F). Do not use Lumizyme after the expiration date on the vial.

The reconstituted and diluted solution should be administered without delay. If immediate use is not possible, the reconstituted and diluted solution is stable for up to 24 hours at 2°C to 8°C (36°F to 46°F). Storage of the reconstituted solution at room temperature is not recommended. The reconstituted and diluted alglucosidase alfa solution should be protected from light. Do not freeze or shake.

Alglucosidase alfa does not contain any preservatives. Vials are single-use only. Discard any unused product.

Pricing Information
Call 1-800-745-4447, option 1.

General Terms and Conditions
Net 90 days, FOB destination, freight pre-paid.

Execution of a payment agreement is required prior to the purchase of Lumizyme.

Shipping and Delivery
Lumizyme is available directly through Sanofi Genzyme or its distributors.

While most orders can be fulfilled for next-day delivery, orders should be placed as soon as possible to facilitate on-time delivery.

Call Sanofi Genzyme Customer Operations at 1-800-745-4447, option 1 for more information on ordering Lumizyme. Sanofi Genzyme's hours of operation are Monday–Friday, 8:00 a.m. to 6:00 p.m. Eastern Time.

Returned Goods
Lumizyme is a non-returnable product, except in cases of Sanofi Genzyme shipping error, product defect, or untreated patient. Sanofi Genzyme reserves the right to review other return requests on a case-by-case basis and may subsequently allow returns at its sole discretion. All returns require prior authorization from Sanofi Genzyme. Call Sanofi Genzyme Customer Operations at 1-800-745-4447, option 1 for return authorization. Lumizyme Return Goods Authorization Policy is available upon request.

Billing Codes
The following is provided for informational purposes only and is not intended to substitute for the physician's independent diagnosis or treatment of each patient. Providers are responsible for the accuracy and validity of any claims, invoices, and related documentation submitted to payers. Physicians should contact the payer if they have any specific questions about coverage or payment. Any specific guidance or direction on the submission of claims offered by the payer supersedes the codes listed below. Use of the following codes does not guarantee reimbursement.

Billing Codes for Lumizyme

ICD-10-CM	E74.02 Pompe Disease
NDC	58468-0160-1 (Carton of one single-use vial) 58468-0160-2 (Carton of ten single-use vials)
HCPCS	J0221 Injection, alglucosidase alfa (Lumizyme), 10 mg
CPT	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

NDC 58468-0160-1 (Carton of one single-use vial)
NDC 58468-0160-2 (Carton of ten single-use vials)
Rx only.

Please see additional Important Safety Information on reverse side and accompanying full Prescribing Information, including Boxed Warning.

www.Lumizyme.com

Lumizyme®
(alglucosidase alfa)

ADDITIONAL IMPORTANT SAFETY INFORMATION
See reverse side for Boxed Warning

WARNINGS AND PRECAUTIONS

Anaphylaxis and Hypersensitivity Reactions: Life-threatening anaphylaxis and hypersensitivity reactions have been observed in some patients during and after treatment with alglucosidase alfa. If anaphylaxis or severe hypersensitivity reactions occur, immediately discontinue infusion and institute appropriate medical treatment. Appropriate medical support and monitoring measures should be available during infusion.

Immune-Mediated Reactions: Monitor patients for the development of systemic immune-mediated reactions involving skin and other organs.

Risk of Acute Cardiorespiratory Failure: Patients with acute underlying respiratory illness and compromised cardiac and/or respiratory function may be at risk of acute cardiorespiratory failure. Caution should be exercised when administering alglucosidase alfa to patients susceptible to fluid volume overload. Appropriate medical support and monitoring measures should be available during infusion and some patients may require longer observation times.

Risk of Cardiac Arrhythmia and Sudden Cardiac Death during General Anesthesia for Central Venous Catheter Placement: Caution should be used when administering general anesthesia for the placement of a central venous catheter intended for alglucosidase alfa infusion.

Risk of Antibody Development: As with all therapeutic proteins, there is potential for immunogenicity. There is some evidence to suggest that some patients who develop high and sustained IgG antibody titers may experience reduced clinical efficacy. Patients should be monitored for IgG antibody formation every 3 months for 2 years and then annually thereafter.

ADVERSE REACTIONS

The most frequently reported adverse reactions (≥ 5%) in clinical trials were hypersensitivity reactions and included: anaphylaxis, rash, pyrexia, flushing/feeling hot, urticaria, headache, hyperhidrosis, nausea, cough, decreased oxygen saturation, tachycardia, tachypnea, chest discomfort, dizziness, muscle twitching, agitation, cyanosis, erythema, hypertension/increased blood pressure, pallor, rigors, tremor, vomiting, fatigue, and myalgia.

USE IN SPECIFIC POPULATIONS

Pregnancy: Based on animal data, alglucosidase alfa may cause fetal harm.

To report SUSPECTED ADVERSE REACTIONS, contact Sanofi Genzyme at 1-800-745-4447 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Please see the **Full Prescribing Information** for complete details, including **boxed WARNING**.

Affix PI here

SANOFI GENZYME

www.Lumizyme.com

Sanofi Genzyme
500 Kendall Street
Cambridge, MA 02142 U.S.A.
1-800-745-4447, option 2
Fax 1-800-737-3642 or 1-617-591-7178
Monday - Friday 8:00 am–6:00 pm ET

GZUS.LUMI.14.11.1207(2)