

## INDICATION

Cerezyme® (imiglucerase for injection) is indicated for long-term enzyme replacement therapy for pediatric and adult patients with a confirmed diagnosis of type 1 Gaucher disease that results in one or more of the following conditions:

- anemia
- thrombocytopenia
- bone disease
- hepatomegaly or splenomegaly



## DOSAGE

Dosage of Cerezyme® should be individualized to each patient. Initial dosages range from 2.5 U/kg of body weight 3 times a week to 60 U/kg once every 2 weeks. 60 U/kg every 2 weeks is the dosage for which the most data are available. Disease severity may dictate that treatment be initiated at a relatively high dose or relatively frequent administration. Dosage adjustments should be made on an individual basis and may increase or decrease, based on achievement of therapeutic goals as assessed by routine comprehensive evaluations of the patient's clinical manifestations. Experience with doses up to 240 U/kg every 2 weeks have been reported. At that dose, there have been no reports of obvious toxicity.

## HOW SUPPLIED

Cerezyme® is supplied as a sterile, non-pyrogenic lyophilized product. Cerezyme® 200 unit vial is supplied in single-use, clear Type I glass vials. The 200 unit vial closure consists of a siliconized butyl stopper and an aluminum seal with a teal plastic flip-off cap. Cerezyme® 400 unit vial is supplied in single-use, clear Type I glass vials. The 400 unit vial closure consists of a siliconized butyl stopper and an aluminum seal with a red plastic flip-off cap.

## STORAGE

Store Cerezyme® vials under refrigeration between 2° – 8°C (36° – 46°F). DO NOT USE Cerezyme® after the expiration date on the vial.

## IMPORTANT SAFETY INFORMATION

Adverse reactions related to Cerezyme® (imiglucerase for injection) administration have been reported in less than 15% of patients. Each of the following events occurred in less than 2% of the total patient population. Reported adverse events include nausea, vomiting, abdominal pain, diarrhea, rash, fatigue, headache, fever, dizziness, chills, backache, and tachycardia. Adverse events associated with the route of administration include discomfort, pruritus, burning, swelling or sterile abscess at the site of venipuncture. Symptoms suggestive of hypersensitivity include anaphylactoid reaction, pruritus, flushing, urticaria, angioedema, chest discomfort, dyspnea, coughing, cyanosis and hypotension. Approximately 15% of patients have developed IgG antibodies; periodic monitoring is suggested. Side effects should be reported promptly to Genzyme Medical Information at 1-800-745-4447 (option 2). To learn more, please see full prescribing information, or contact Genzyme at 1-800-745-4447 (option 2).

## GENERAL TERMS & CONDITIONS

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

## PRICING INFORMATION

Call 1-800-745-4447.

## SHIPPING AND DELIVERY

Cerezyme® is available directly through Genzyme or through its distributors. Distributors can ship Cerezyme® and then bill the patient's insurance company directly. Genzyme's shipping hours are Monday – Friday 8:00 am – 5:00 pm EST. Call Genzyme Therapeutics Product Services at 1-617-768-9000 or toll-free at 1-800-745-4447 for more information on ordering Cerezyme®.

## RETURNED GOODS

Cerezyme® 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 at its sole discretion.

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

## BILLING CODES

The following codes may be used to communicate services rendered when filing claims for Cerezyme®, and are provided for informational purposes only. Note that any specific guidance or direction on the submission of claims offered by the payer supercede the codes listed below, and providers are responsible for the accuracy of any claims, invoices, and related documentation submitted to payers.

ICD-9-CM	272.7 – Lipidosis (Gaucher disease)
NDC	58468-1983-1 (200 units) 58468-4663-1 (400 units)
HCPCS	J1785 – Cerezyme® - injection, imiglucerase, per unit
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 requiring a HCPCS code

Please refer to the Cerezyme® Billing Guide for more information.

## PRODUCT INFORMATION

Please see accompanying full prescribing information.

**NDC 58468-1983-1 (200 units), 58468-4663-1 (400 units)**

Rx only.

