CEREZYME- imiglucerase injection, powder, lyophilized, for solution
Genzyme Corporation

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use CEREZYME® safely and effectively. See full prescribing information for CEREZYME.

CEREZYME (imiglucerase) for injection, for intravenous use

Initial U.S. Approval: 1994

WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS

***See full prescribing information for complete boxed warning*.**

- **Anaphylaxis has occurred during the early course of enzyme replacement therapy and after extended duration of therapy. (5.1)**
- **Initiate Cerezyme in a healthcare setting with appropriate medical monitoring and support measures, including access to cardiopulmonary resuscitation equipment. (5.1)**
- **If a severe hypersensitivity reaction (e.g., anaphylaxis) occurs, discontinue Cerezyme and immediately initiate appropriate medical treatment, including use of epinephrine. (5.1)**

RECENT MAJOR CHANGES

Boxed Warning	7/2024
Dosage and Administration (2.1)	7/2024
Warnings and Precautions (5.1, 5.2)	7/2024, 12/2024

INDICATIONS AND USAGE

Cerezyme is a hydrolytic lysosomal glucocerebrosidase-specific enzyme indicated for treatment of adults and pediatric patients 2 years of age and older with Type 1 Gaucher disease that results in one or more of the following conditions: anemia, thrombocytopenia, bone disease, hepatomegaly or splenomegaly. (1)

DOSAGE AND ADMINISTRATION

- Administration of Cerezyme should be supervised by a healthcare provider knowledgeable in the management of hypersensitivity reactions including anaphylaxis. (2.1)
- The recommended dosage ranges from 2.5 units/kg three times a week to 60 units/kg once every two weeks. (2.2)
- Cerezyme is administered by intravenous infusion over 1 to 2 hours. (2.2)
- Titrate the dosage based on clinical manifestations of disease and therapeutic goals for the patient. (2.2)
- See the full prescribing information for preparation and administration instructions. (2.3)

DOSAGE FORMS AND STRENGTHS

For injection: 400 units of imiglucerase as a lyophilized powder in a single-dose vial. (3)

CONTRAINDICATIONS

None. (4)

WARNINGS AND PRECAUTIONS

Infusion-Associated Reactions (IAR): If an IAR occurs, decreasing the infusion rate, temporarily stopping the infusion, and/or administering appropriate treatment may ameliorate the symptoms. (5.2)

ADVERSE REACTIONS

- Adverse reactions reported in adults include back pain, chills, dizziness, fatigue, headache, hypersensitivity reactions, nausea, pyrexia, and vomiting. (6.1)
- Adverse reactions reported in pediatric patients 2 years of age and older are similar to adults. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Genzyme at 1-800-633-1610 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
See 17 for PATIENT COUNSELING INFORMATION.

Revised: 12/2024

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING 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 Cerezyme 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 Cerezyme 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)]*.

1 INDICATIONS AND USAGE

Cerezyme is indicated for treatment of adults and pediatric patients 2 years of age and older with Type 1 Gaucher disease that results in one or more of the following conditions:

- anemia
- thrombocytopenia
- bone disease
- hepatomegaly or splenomegaly

2 DOSAGE AND ADMINISTRATION

2.1 Recommendations Prior to Cerezyme Treatment

Administration of Cerezyme should be supervised by a healthcare provider knowledgeable in the management of hypersensitivity reactions including anaphylaxis *[see Warnings and Precautions (5.1)]*.

Initiate Cerezyme in a healthcare setting with appropriate medical monitoring and support measures, including access to cardiopulmonary resuscitation equipment *[see Warnings and Precautions (5.1)]*.

For patients who experience hypersensitivity reactions to Cerezyme, premedicate with antihistamines and/or corticosteroids. Monitor patients for the occurrence of new hypersensitivity reactions *[see Warnings and Precautions (5.1)]*.

2.2 Recommended Dosage

Therapy with Cerezyme should be directed by physicians knowledgeable in the management of patients with Gaucher disease.

The recommended dosage of Cerezyme based upon disease severity ranges from 2.5 units/kg three times a week to 60 units/kg once every two weeks. For patients weighing 18 kg and greater, infuse the diluted Cerezyme solution over 1 to 2 hours. For patients

weighing less than 18 kg, infuse the diluted Cerezyme solution over 2 hours *[see Dosage and Administration (2.3)]*. Titrate the dosage based on clinical manifestations of disease and therapeutic goals for the patient.

2.3 Preparation and Administration Instructions

Cerezyme does not contain preservatives.

Reconstitution and Dilution Using Aseptic Technique

1. Determine the number of Cerezyme vials to be reconstituted based on the individual patient's dosage regimen and remove vial(s) from the refrigerator.
2. Reconstitute each 400 unit vial of Cerezyme by slowly injecting 10.2 mL of Sterile Water for Injection, USP, down the inside wall of each vial.
3. Roll and tilt the vial to allow the powder to dissolve completely. Each vial will yield a concentration of Cerezyme after reconstitution of 40 units/mL. Visually inspect the solution after reconstitution for particulate matter and discoloration. Discard if opaque particles or discoloration are observed.
4. Withdraw up to 10 mL per vial. Discard unused portion.
5. Dilute the Cerezyme solution promptly with 0.9% Sodium Chloride Injection, USP, to a final volume of 100 to 200 mL. For patients weighing less than 18 kg, dilute Cerezyme to a final volume of 100 mL. Gently invert infusion bag to mix the solution, avoiding vigorous shaking and agitation.
   Visually inspect the solution prior to administration of the final product for particulate matter and discoloration. Slight flocculation of protein particles (described as thin translucent fibers) may occur after dilution and does not affect the quality of the product.
6. For patients weighing 18 kg and greater, infuse the diluted Cerezyme solution over 1 to 2 hours. For patients weighing less than 18 kg, infuse the diluted Cerezyme solution over 2 hours.
7. The diluted solution may be filtered through an in-line low protein-binding 0.2 µm filter during administration.

Storage and Handling

- If the reconstituted Cerezyme vial is not used immediately, store at room temperature at 68°F to 77°F (20°C to 25°C) or refrigerated at 36°F to 46°F (2°C to 8°C) for up to 12 hours.
- After dilution, Cerezyme is stable for up to 24 hours when stored refrigerated at 36°F to 46°F (2°C to 8°C).

3 DOSAGE FORMS AND STRENGTHS

For injection: 400 units of imiglucerase as a white to off-white lyophilized powder in a single-dose vial for reconstitution.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions Including Anaphylaxis

Life-threatening hypersensitivity reactions, including anaphylaxis, have been reported in patients treated with enzyme replacement therapies, including Cerezyme. In addition, other hypersensitivity reactions have included pruritus, flushing, urticaria, angioedema, chest discomfort, dyspnea, cough, cyanosis, tachycardia, and hypotension *[see Adverse Reactions (6.1)]*. Patients with antibody to imiglucerase have a higher risk of hypersensitivity reactions. Conversely, not all patients with symptoms of hypersensitivity have detectable IgG antibody. Consider periodic monitoring of patients during the first year of treatment for IgG antibody formation *[see Adverse Reactions (6.2)]*.

Anaphylaxis has occurred during the early course of enzyme replacement therapy and after extended duration of therapy. Administration of Cerezyme should be supervised by a healthcare provider knowledgeable in the management of hypersensitivity reactions including anaphylaxis. Initiate Cerezyme 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 Cerezyme and immediately initiate appropriate medical treatment, including use of epinephrine. Consider the risks and benefits of readministering Cerezyme to individual patients following a severe reaction. If the decision is made to readminister the product, consider reducing the rate of infusion and pretreat with antihistamines and/or corticosteroids and monitor patients for the occurrence of new signs and symptoms of a severe hypersensitivity reaction.

Inform patients of the symptoms of life-threatening hypersensitivity reactions, including anaphylaxis and to seek immediate medical care should symptoms occur.

5.2 Infusion-Associated Reactions

Infusion-associated reactions (IARs) such as angioedema, pruritus, rash, urticaria, chest discomfort, chills, fatigue, infusion-site burning, infusion-site discomfort, infusion-site swelling, pyrexia and hypertension have been observed in patients treated with Cerezyme *[see Adverse Reactions (6.1)]*.

If an IAR occurs, decreasing the infusion rate, temporarily stopping the infusion, and/or administering antihistamines and/or antipyretics may ameliorate the symptoms. Closely monitor patients who have experienced IARs when re-administering Cerezyme.

6 ADVERSE REACTIONS

6.1 Clinical Trials and Postmarketing Experience

The following adverse reactions associated with the use of imiglucerase were identified in clinical studies or postmarketing reports. Because some of these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

System Organ Class	**Adverse Reactions**
Nervous system disorders	dizziness, headache

Cardiac disorders	tachycardia
Vascular disorders	cyanosis,* flushing,* hypotension,* hypertension*
Respiratory, thoracic and mediastinal disorders	cough,* dyspnea,* pneumonia, pulmonary hypertension
Gastrointestinal disorders	abdominal pain, diarrhea, nausea, vomiting
Immune system disorders	anaphylaxis,* hypersensitivity
Skin and subcutaneous tissue disorders	angioedema,* pruritus,* rash, urticaria*
Musculoskeletal and connective tissue disorders	back pain
General disorders and administration site conditions	chest discomfort,* chills, fatigue, infusion-site burning, infusion-site discomfort, infusion-site swelling, pyrexia

* Signs and symptoms suggestive of hypersensitivity reactions including anaphylaxis *[see Warnings and Precautions (5.1)]* and other infusion-associated reactions *[see Warnings and Precautions (5.2)]*.

Adverse reactions reported in pediatric patients 2 years of age and older were similar to adults.

6.2 Immunogenicity

As with all therapeutic proteins, there is potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies in the studies described below with the incidence of antibodies in other studies or to other imiglucerase products may be misleading.

Approximately 15% of patients treated and tested to date have developed IgG antibody to Cerezyme during the first year of therapy. Patients who developed IgG antibody did so largely within 6 months of treatment and rarely developed antibodies to Cerezyme after 12 months of therapy. Approximately 46% of patients with detectable IgG antibodies experienced symptoms of hypersensitivity. Patients with antibody to Cerezyme have higher risk of hypersensitivity reaction *[see Warnings and Precautions (5.1)]*. Patients who developed IgG antibody to Cerezyme had increased elimination half-life compared to patients without antibody *[see Clinical Pharmacology (12.3)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women

exposed to Cerezyme during pregnancy. Pregnant women exposed to Cerezyme and health care providers are encouraged to contact the Gaucher patient registry at 1-800-745-4447, extension 15500 or visit www.registrynxt.com.

Risk Summary

Available data on more than 500 pregnancies from the international Gaucher Disease registry, postmarketing reports, published observational studies and case reports with Cerezyme or non–US-licensed imiglucerase use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. There are risks associated with symptomatic Type I Gaucher disease in pregnancy *(see Clinical Considerations)*. No animal reproduction studies have been conducted with imiglucerase.

The estimated background risk of major birth defects and miscarriage in the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Disease-associated Maternal and/or Embryo/Fetal Risk

Pregnancy may exacerbate existing Type 1 Gaucher disease symptoms or result in new disease manifestations. Untreated symptomatic Type 1 Gaucher may lead to complications during pregnancy, including hepatosplenomegaly, which can interfere with the normal growth of a pregnancy and thrombocytopenia, which can lead to excessive bleeding.

8.2 Lactation

Risk Summary

Available published literature suggests a small amount of imiglucerase is present in breast milk immediately following an infusion of imiglucerase. Published case reports and postmarketing reports of breastfed infants have not reported adverse effects due to Cerezyme exposure. There are no data available on the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Cerezyme and any potential adverse effects on the breastfed infant from imiglucerase or from the underlying maternal condition.

Lactating women with Gaucher disease treated with Cerezyme should be encouraged to enroll in the Gaucher patient registry *[see Use in Specific Populations (8.1)]*.

8.4 Pediatric Use

The safety and effectiveness of Cerezyme for treatment of Type 1 Gaucher disease that results in one or more of the following conditions: anemia, thrombocytopenia, bone disease, hepatomegaly or splenomegaly have been established in pediatric patients 2 years of age and older. Use of Cerezyme for this indication is supported by evidence from adequate and well-controlled studies of Cerezyme and alglucerase in adults and pediatric patients 12 years of age and older, with additional data obtained from the medical literature and from postmarketing experience in pediatric patients as young as 2 years of age *[see Adverse Reactions (6.1), Clinical Studies (14)]*.

The safety and effectiveness of Cerezyme have not been established in pediatric patients younger than 2 years of age.

11 DESCRIPTION

Imiglucerase is a hydrolytic lysosomal glucocerebrosidase-specific enzyme. It is an analogue of the human enzyme b-glucocerebrosidase (b-D-glucosyl-N-acylsphingosine glucohydrolase, E.C. 3.2.1.45), produced by recombinant DNA technology using mammalian cell culture (Chinese hamster ovary). Purified imiglucerase is a monomeric glycoprotein of 497 amino acids, containing 4 N-linked glycosylation sites (Mr=60,430). Imiglucerase differs from placental glucocerebrosidase by one amino acid at position 495, where histidine is substituted for arginine. The oligosaccharide chains at the glycosylation sites have been modified to terminate in mannose sugars. The modified carbohydrate structures on imiglucerase are somewhat different from those on placental glucocerebrosidase.

Cerezyme (imiglucerase) for injection is intended for intravenous use. It is supplied as a sterile, nonpyrogenic, white to off-white lyophilized powder for reconstitution with Sterile Water for Injection, USP. Each single-dose vial contains 424 units imiglucerase, mannitol (340 mg), polysorbate 80, NF (1.06 mg), and sodium citrates: disodium hydrogen citrate (36 mg) and trisodium citrate (104 mg).

An enzyme unit (U) is defined as the amount of enzyme that catalyzes the hydrolysis of 1 micromole of the synthetic substrate para-nitrophenyl-b-D-glucopyranoside (pNP-Glc) per minute at 37°C. Reconstituted solutions have a pH of approximately 6.1.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Gaucher disease is characterized by a deficiency of β-glucocerebrosidase activity, which results in accumulation of glucocerebroside in various tissues including liver, spleen, and bone marrow. The mannose sugars on imiglucerase mediate binding to and internalization by cells including macrophages. Cerezyme catalyzes the hydrolysis of glucocerebroside to glucose and ceramide.

12.2 Pharmacodynamics

No formal pharmacodynamic studies have been conducted with Cerezyme.

12.3 Pharmacokinetics

During one-hour intravenous infusions of four doses (7.5, 15, 30, 60 units/kg) of Cerezyme, steady-state enzymatic activity was achieved by 30 minutes. Following infusion, the half-life of plasma enzymatic activity ranged from 3.6 to 10.4 minutes. Plasma clearance ranged from 9.8 to 20.3 mL/min/kg (mean ± SD, 14.5 ± 4.0 mL/min/kg). The volume of distribution corrected for weight ranged from 0.09 to 0.15 L/kg (mean ± SD, 0.12 ± 0.02 L/kg). These variables do not appear to be influenced by dose or duration of infusion. However, only one or two patients were studied at each dose level and infusion rate.

Antidrug Antibody Effects on Pharmacokinetics

In patients who developed IgG antibody to Cerezyme, an apparent effect on serum enzyme levels resulted in diminished volume of distribution and clearance and increased elimination half-life compared to patients without antibody *[see Adverse Reactions (6.2)]*.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Long-term studies in animals to evaluate carcinogenic potential have not been performed with imiglucerase.

Mutagenesis

Imiglucerase was negative in the Ames test.

Impairment of Fertility

An animal fertility study was not performed. No histopathological findings on reproductive organs were observed in 13-week toxicity studies conducted in rats and monkeys.

14 CLINICAL STUDIES

Study RC 91-0110 was a randomized, double-blind, active-controlled study of 30 patients (17 male and 13 female), aged 12 to 69 years (mean age of 38 years in the Cerezyme group and mean age of 28 years in the alglucerase group at baseline), with Gaucher disease type 1 and a hemoglobin of at least 1 g/dL below the lower age limit for age and sex. Patients were randomized 1:1 to receive either Cerezyme 60 units/kg every other week or alglucerase for 6 months. Primary efficacy parameters were an increase in hemoglobin concentration of at least 1 g/dL, increase in platelet count and decrease in spleen and liver volume at 6 months. Efficacy results are shown in Table 1.

Table 1: Change from Baseline to Month 6 in Clinical Efficacy Parameters in a Randomized, Double-Blind Active-Controlled Trial of Cerezyme Compared to Alglucerase in Patients 12 Years of Age and Older with Gaucher Disease Type 1

Clinical Parameter		Cerezyme (N=15)	Alglucerase (N=15)	Difference (Cerezyme – Alglucerase) [95% CI]*
Hemoglobin concentration (g/dL)	Baseline	10.7	10.9	–
	Absolute Change from Baseline	1.9	1.6	0.3 [-0.6, 1.3]
Platelet count ($\times 10^3/mL^3$)	Baseline	68.5	74.2	–
	Absolute Change from Baseline	22.7	15.8	6.9 [-10.4, 24.1]
	Baseline	2521	2788	–

Liver volume (mL)	Absolute Change from Baseline	-310	-307	-3 [-246, 240]
	Percent Change from Baseline (%)	-11	-10	-1 [-9, 7]
Spleen volume (mL)	Baseline	2369	2603	–
	Absolute Change from Baseline	-902	-874	-28 [-652, 596]
	Percent Change from Baseline (%)	-35	-30	-5 [-14, 4]

* Confidence intervals were calculated using the t distribution (appropriate for small sample sizes) and the standard error of the difference in sample means (i.e. the pooled estimate of the common standard deviation, computed as the weighted average of the standard deviations in the two treatment groups); there was no evidence that the assumption of equal variances between the groups was violated.

Bone x-rays showed improvements in cortical thickness and lucencies in 7 of 11 Cerezyme treated patients.

In study RC 92-0501, twenty-nine patients continued treatment for total duration of 24 months. Patients were unblinded at 9 months and allowed to cross-over to Cerezyme treatment. At 24 months, mean increase in hemoglobin was 2.4 g/dL, mean increase in platelet count was 40 $\times 10^3/mL^3$, mean change in liver volume was -20%, and mean change in spleen volume was -57%.

16 HOW SUPPLIED/STORAGE AND HANDLING

Cerezyme (imiglucerase) for injection, 400 units as a white to off-white lyophilized powder in a single-dose vial: NDC 58468-4663-1

Store refrigerated at 2°C to 8°C (36°F to 46°F).

For storage of reconstituted and diluted solution *[see Dosage and Administration (2.2)]*.

17 PATIENT COUNSELING INFORMATION

Hypersensitivity Reactions Including Anaphylaxis and Infusion-Associated Reactions

Advise patients and caregivers that life-threatening hypersensitivity reactions, including anaphylaxis, and infusion reactions may occur with Cerezyme treatment.

Advise patients and caregivers that anaphylaxis has occurred during the early course of enzyme replacement therapy and after extended duration of therapy.

Inform patients and caregivers of the symptoms of life-threatening hypersensitivity reactions, including anaphylaxis, and IARs and to seek immediate medical care should symptoms occur *[see Warnings and Precautions (5.1, 5.2)]*.

Patient Registry

Inform patients and caregivers that the Gaucher patient registry has been established in order to better understand the variability and progression of Gaucher disease and to continue to monitor and evaluate long-term treatment effects of Cerezyme. A pregnancy sub-registry will also monitor the effects of Cerezyme on pregnant women

and their offspring *[see Use in Specific Populations (8.1)]*. Encourage patients and caregivers to participate in the Gaucher patient registry. Advise patients that their participation is voluntary and may involve long-term follow-up. For information regarding the registry program, visit www.registrynxt.com or call 1-800-745-4447, extension 15500.

Manufactured by:
Genzyme Corporation
Cambridge, MA 02141
A SANOFI COMPANY
U.S. License Number: 1596

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PRINCIPAL DISPLAY PANEL - 400 Unit Vial Carton

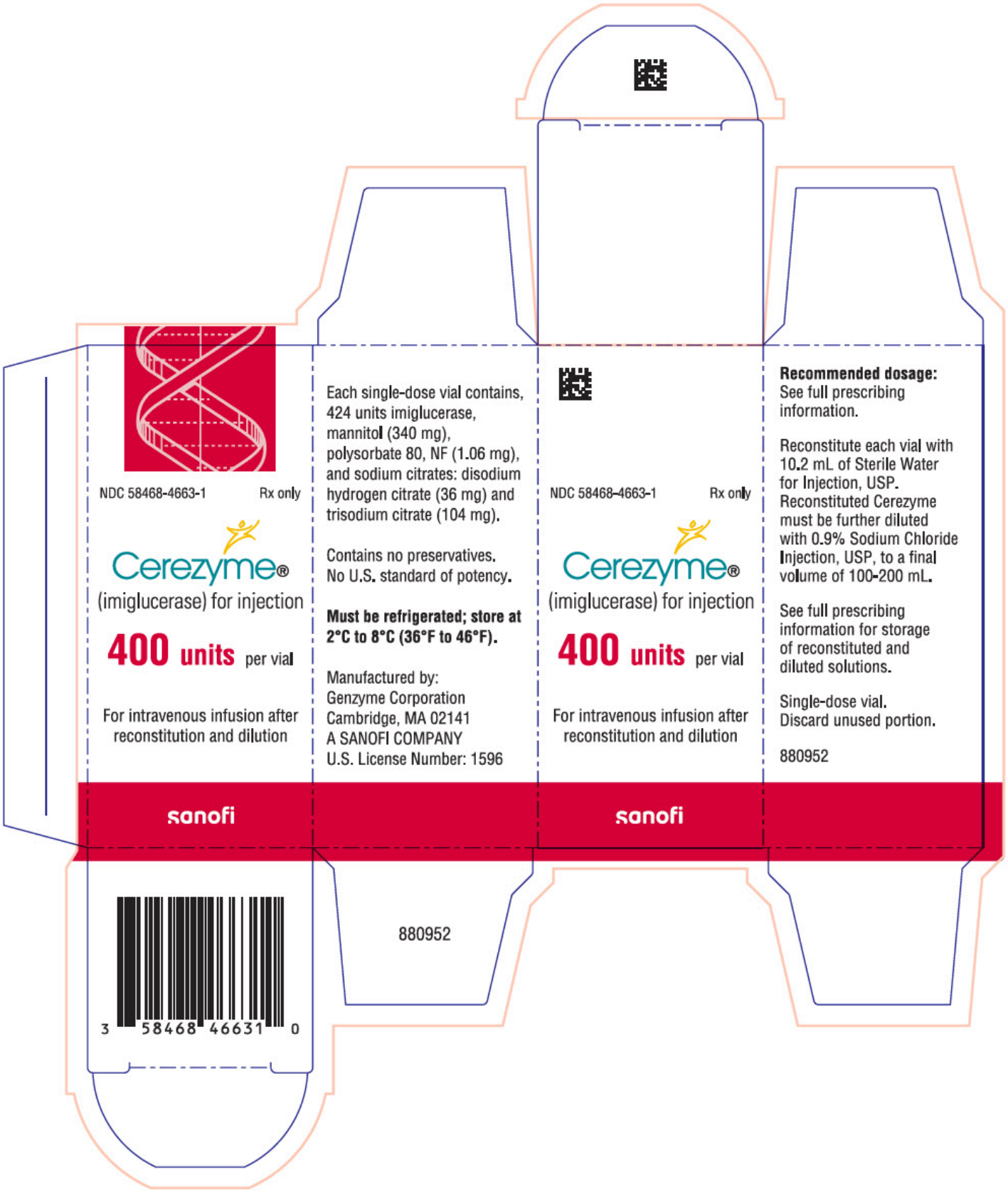
NDC 58468-4663-1
Rx only

Cerezyme®
(imiglucerase) for injection

400 units per vial

For intravenous infusion after
reconstitution and dilution

sanofi



CEREZYME

imiglucerase injection, powder, lyophilized, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:58468-4663
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
IMIGLUCERASE (UNII: Q6U6J48BWY) (IMIGLUCERASE - UNII:Q6U6J48BWY)	IMIGLUCERASE	40 U in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
MANNITOL (UNII: 3OWL53L36A)	32.08 mg in 1 mL
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	9.81 mg in 1 mL
DISODIUM HYDROGEN CITRATE (UNII: 6FO62KCQ7A)	3.4 mg in 1 mL
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	0.1 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58468-4663-1	1 in 1 CARTON	05/23/1994	
1		10 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA020367	05/23/1994	

Labeler - Genzyme Corporation (025322157)

Establishment

Name	Address	ID/FEI	Business Operations
Genzyme Ireland Limited		985127419	ANALYSIS(58468-4663) , MANUFACTURE(58468-4663) , PACK(58468-4663) , LABEL(58468-4663)

Establishment

Name	Address	ID/FEI	Business Operations
Genzyme Corporation		050424395	PACK(58468-4663) , LABEL(58468-4663)

Establishment

Name	Address	ID/FEI	Business Operations
Charles River Laboratories, Inc.		078495006	ANALYSIS(58468-4663)

Establishment

Name	Address	ID/FEI	Business Operations
Eurofins Biopharma Product Testing Ireland Limited		238239933	ANALYSIS(58468-4663)

Establishment

Name	Address	ID/FEI	Business Operations
Genzyme Corporation		117450412	ANALYSIS(58468-4663) , MANUFACTURE(58468-4663) , API MANUFACTURE(58468-4663)

Establishment

Name	Address	ID/FEI	Business Operations
Genzyme Corporation		968302658	ANALYSIS(58468-4663)

Establishment

Name	Address	ID/FEI	Business Operations
Genzyme Corporation		034378252	ANALYSIS(58468-4663) , MANUFACTURE(58468-4663) , API MANUFACTURE(58468-4663)