

Choose Confidently Choose Cerezyme

When considering an ERT to treat
the non-CNS symptoms of Gaucher
disease types 1 and 3


Cerezyme.
(imiglucerase) for injection



Not an actual patient.

Cerezyme is the #1 prescribed ERT for Gaucher disease type 1 in the US*

*Based on publicly available data as of September 2025.

Cerezyme is the only treatment for Gaucher disease type 1 with over 30 years of time-tested and enduring results. Cerezyme is also the first and only FDA-approved treatment for the non-central nervous system (CNS) symptoms of Gaucher disease type 3.

CNS=central nervous system; ERT=enzyme replacement therapy; FDA=Food and Drug Administration.

www.cerezyme.com

Indication:

Cerezyme® (imiglucerase) for injection is indicated for the treatment of non-central nervous system (CNS) manifestations of Type 1 or Type 3 Gaucher disease in adult and pediatric patients.

Important Safety Information

WARNING: SEVERE ALLERGIC REACTIONS

Allergic reactions, including severe reactions that may be serious or life-threatening (known as anaphylaxis), have occurred during the early course and after repeated treatment with CEREZYME.

Your healthcare professional should initiate CEREZYME in a healthcare setting with appropriate medical monitoring and support measures. If a severe allergic or anaphylactic reaction occurs, your healthcare professional will immediately stop the infusion and provide appropriate medical treatment.

Seek immediate medical care should symptoms occur.

Please see accompanying Full Prescribing Information, including **Boxed WARNING**.

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Not an actual patient.

Starting Your Journey With Cerezyme® (imiglucerase) for Injection

If you have been prescribed Cerezyme for Gaucher disease, this guide includes important information to help you better understand your treatment. In the following pages, you will also learn about additional resources available to you that may help with managing your Gaucher disease.

Cerezyme is the only FDA-approved treatment for the non-CNS symptoms of Gaucher disease types 1 and 3.

If you have any questions after reading through this brochure, please visit [Cerezyme.com](https://www.cerezyme.com) or talk to your doctor.

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What Is Gaucher Disease?

Understanding Gaucher disease

Gaucher (pronounced go-shay) disease is a rare, progressive, inherited condition that causes a fatty substance, called glucosylceramide (gloo-ko-sil-saramide, also called GL-1), to build up in various tissues, including the liver, spleen, bone marrow, and in some cases, the brain.

Gaucher disease has a range of symptoms and severity. Gaucher disease can be divided into 3 types (type 1, type 2, and type 3) based on the presence of neurologic symptoms and how quickly they progress. There are no FDA-approved treatments for Gaucher disease type 2.

Taking a closer look at Gaucher disease types 1 and 3

TYPE

1

The most common type in the US. People with Ashkenazi Jewish heritage are more likely to have it.

TYPE

3

A less common type that affects both the brain and the body. Typically beginning in childhood, the body symptoms are similar to those in type 1.

Gaucher disease is a genetic condition that can be passed down through families. If you have been diagnosed with Gaucher disease, it's important to talk to your family members about genetic testing.

Not actual patients.

How to get tested



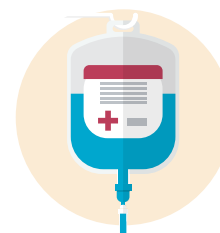
Gaucher disease can be detected with a blood test.

- Enzyme testing is the best way to establish a diagnosis of Gaucher disease
- Genetic testing can confirm the diagnosis and may provide additional details about the disease

Treating Gaucher disease type 1 and type 3

The goal of treatment is to reduce or prevent the buildup of GL-1. Existing therapies can treat organ-, blood-, and bone-related symptoms of Gaucher disease types 1 and 3. However, there are no FDA-approved treatments for neurologic symptoms of Gaucher disease. Treatment outcomes may vary among patients.

2 treatment approaches



Enzyme Replacement Therapy (ERT)

- Available to treat the non-CNS symptoms of Gaucher disease type 1 and type 3
- Intravenous (IV) infusions
- Adds a modified version of the enzyme to help your body break down GL-1



Substrate Reduction Therapy (SRT)

- Available for Gaucher disease type 1 only
- Oral medicine taken daily
- Reduces the amount of GL-1 that is produced

Talk to your doctor about treatment options; your doctor will decide what treatment is right for you.

About Cerezyme® (imiglucerase) for Injection

What is Cerezyme?

People with Gaucher disease may not have enough of an enzyme called glucocerebrosidase (also known as acid beta glucosidase) that breaks down a fatty substance called glucosylceramide, or GL-1. Cerezyme is a modified form of glucocerebrosidase, and it works to reduce the buildup of GL-1 in the body.



Cerezyme is the longest-standing and trusted treatment for Gaucher disease type 1, having helped thousands of patients across the United States. It is also the first and only FDA-approved treatment for the non-CNS symptoms of Gaucher disease type 3.

How Cerezyme has been proven to help

Cerezyme has helped adults and children with Gaucher disease type 1 and type 3 by improving key disease symptoms over the long term, including:



Reduced platelets in the blood and low red blood cell count



Enlarged spleen and liver (known as splenomegaly and hepatomegaly, respectively)



Bone pain, bone crisis,* low bone mineral density (BMD), and delayed growth**

*Bone crisis is an episode of severe bone pain that lasts for more than 3 days and may be accompanied with other symptoms, such as fever.

**Bone mineral density, or bone mass, is the amount of minerals in your bones.

Important Safety Information (continued)

Cerezyme can cause serious side effects including:

Allergic Reactions (Including Anaphylaxis) and Infusion-Associated Reactions (IARs):

Signs of an allergic reaction reported during or shortly after an infusion included itching, flushing, hives, swelling under the skin, chest discomfort, shortness of breath, coughing, a bluish discoloration of the skin due to diminished oxygen, rapid heart rate, and low blood pressure.



Studies show that Cerezyme treatment helped people with Gaucher disease types 1 and 3 by improving certain disease symptoms.

Not an actual patient.

The Studies Behind Cerezyme® (imiglucerase) for Injection

Cerezyme was evaluated in clinical trials for its effectiveness and safety in patients with Gaucher type 1.



A 6-month pivotal clinical trial measured Gaucher-related organ and blood problems during Cerezyme treatment



A 48-month clinical trial measured bone response to Cerezyme treatment in patients with a history of bone problems

Published studies from the International Collaborative Gaucher Group (ICGG) Gaucher Registry support clinical trial findings.



A long-term Gaucher Registry study reviewed how 20 years of Cerezyme treatment affected signs and symptoms of Gaucher disease in adults and children



An 8-year Gaucher Registry study is the largest study on the effects of Cerezyme on organ, blood, and bone problems in children with Gaucher disease

What is the Gaucher Registry?

The Gaucher Registry is an international database sponsored by Sanofi, initiated to keep track of the experiences of people with Gaucher disease. The data from the Gaucher Registry are used to help researchers and physicians understand the impact of Gaucher disease and the effectiveness of long-term treatment. Since 1991, the Gaucher Registry has collected voluntary information from nearly 7,000 people with Gaucher disease worldwide.



6-month pivotal clinical trial

About the study: 30 people with Gaucher disease type 1, aged 12 to 69 years old

- Each person was randomly assigned treatment with Cerezyme or alglucerase
- Neither the people in the study nor the study personnel, including doctors, knew which treatment each person was receiving

The 6-month pivotal clinical trial compared Cerezyme to alglucerase to confirm that both worked similarly to relieve certain disease symptoms, including organ and blood problems, in people with Gaucher disease type 1.*

Alglucerase was the first ERT developed by Genzyme for people with Gaucher disease type 1. Alglucerase is no longer available and was replaced by Cerezyme.

Changes in organ size at 6 months* vs start of study

Liver volume

↓ 11%

average decrease with **Cerezyme** (out of 15 patients)

Spleen volume

↓ 35%

average decrease with **Cerezyme** (out of 15 patients)

Bone X-rays showed improvements in outer layer thickness and density in 7 of 11 Cerezyme-treated patients in the initial analysis period (6 months)

Improvements in red blood cell level and platelet count at 6 months* vs start of study

Red blood cell level

↑ 1.9 g/dL

average increase with **Cerezyme** (out of 15 patients)

Platelet count

↑ 22.7 (x10³/mm³)

average increase with **Cerezyme** (out of 15 patients)

Patients who took alglucerase saw an average of 10% decrease in liver volume, 30% decrease in spleen volume, 1.6 g/dL increase in hemoglobin level, and 15.8 (x 10³/mm³) increase in platelet count.

*At 9 months, all patients were allowed to continue in the study and receive Cerezyme treatment. 29 patients continued treatment for a total duration of 24 months.

Important Safety Information (continued)

Allergic Reactions (Including Anaphylaxis) and Infusion-Associated Reactions (IARs) (continued):

Signs of an infusion reaction included rash, chills, fatigue, infusion-site burning, infusion-site discomfort, or infusion-site swelling, fever, and high blood pressure.

Please see accompanying **Full Prescribing Information, including Boxed WARNING.**





48-month bone clinical trial

About the study: This study included 33 children and adults with Gaucher disease type 1 who reported at least 1 bone problem, such as bone crisis, death of bone tissue, and fractures, and received Cerezyme every 2 weeks for up to 48 months. The study measured bone response, as shown by bone pain, bone crisis, and bone mineral density in the spine and femur (thigh bone).

Long-term effect of Cerezyme on the occurrence of bone pain over 48 months

Start of study

24 out of 33 patients (73%) reported bone pain

After 48 months

9 out of 23 patients (39%) reported bone pain

Long-term effect of Cerezyme on the occurrence of bone crisis over 48 months

Start of study

13 out of 33 patients (39%) had a history of bone crises

The other 20 patients had no history of bone crises

After 48 months

2 out of those 13 patients (15%) experienced a bone crisis during the study

One patient with no bone crisis history experienced a crisis during the study

Over 48 months, patients' bone mineral density improved in the spine and femur

Bone pain was assessed by patient report on a scale: none, very mild, mild, moderate, severe, or extreme. Bone crisis was defined as pain with acute onset requiring immobilization of the affected area, narcotics for pain relief, and may be accompanied by 1 or more of the following: periosteal elevation, elevated white blood cells, fever, or debilitation of >3 days. BMD is a measure of bone health and risk for fracture. Low BMD means weakened bones.

Important Safety Information

Allergic Reactions (Including Anaphylaxis) and Infusion-Associated Reactions (IARs) (continued):

Tell your healthcare professional right away if you experience any reactions. Your healthcare professional may slow or stop the infusion or may lower the next dose. Your healthcare professional may decide to give you antihistamine, anti-fever, and/or steroid medications before your infusions and monitor you for new signs and symptoms of a reaction.



20-year Gaucher Registry study

About the study: This was an observational study where researchers reviewed information that had been collected in the ICGG Gaucher Registry for 475 children and adults with Gaucher disease type 1 who were treated with Cerezyme for about 20 years. Before switching to Cerezyme, some patients in the study received alglucerase—the first ERT developed by Genzyme for people with Gaucher disease type 1.

- Information entry is voluntary, and not all the data on every parameter are available for every patient in the registry. The Gaucher Registry includes patients with a variable range of disease status and management

Over 20 years of treatment, Cerezyme:

Reduced the size of enlarged organs

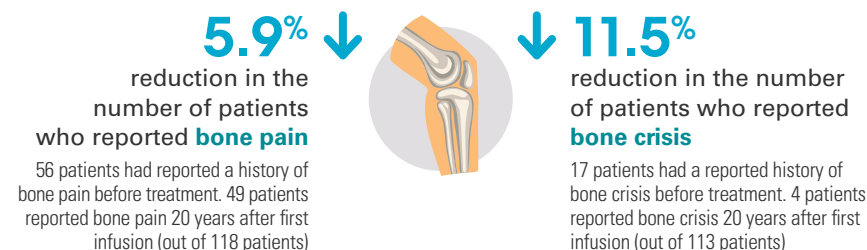
The following data are for Cerezyme-treated patients with intact spleens.



Improved blood problems



Reduced bone problems



Long-term treatment with Cerezyme reduced organ, blood, and certain bone problems.

Please see accompanying **Full Prescribing Information**, including **Boxed WARNING**.





8-year Gaucher Registry pediatric study

About the study: This was an observational study where researchers reviewed data from 884 pediatric patients with Gaucher disease type 1 who were enrolled in the ICGG Gaucher Registry. The study patients had intact spleens and were receiving alglucerase (22.4%) or Cerezyme (77.6%).

- Data up to 8 years after the first treatment infusion or 18 years of age were analyzed
- BMD data were analyzed until 12 years after the first treatment infusion
- Information entry is voluntary and not all the data on every parameter are available for every patient in the registry. The ICGG Registry includes patients with a variable range of disease status and management

Long-term Cerezyme treatment for children with Gaucher disease type 1 was found to:

Reduce the size of enlarged organs

median **liver** volume at baseline was 2.0 MN and 1.1 MN after 8 years on Cerezyme (out of 420 patients)



median **spleen** volume at baseline was 23 MN and 4.8 MN after 8 years on Cerezyme (out of 458 patients)

Improve blood problems

2 g/dL ↑ increase in median **red blood cell** level (out of 771 patients)



baseline **platelet** count was $98 \times 10^3/\text{mm}^3$ and $171 \times 10^3/\text{mm}^3$ after 8 years on Cerezyme (out of 768 patients)

Long-term use of Cerezyme improved height growth for children with Gaucher disease type 1. After 8 years, the patients' median height was not substantially different from the median for the healthy population.



Not actual patients.

Please see accompanying **Full Prescribing Information**, including **Boxed WARNING**.

Cerezyme
(imiglucerase) for injection 13

The Studies Behind Cerezyme[®] (imiglucerase) for Injection (continued)

Cerezyme was evaluated for its effectiveness and safety in patients with Gaucher disease type 3 using data from the ICGG Gaucher Registry.



A 2-year Gaucher Registry long-term study of patients with Gaucher disease type 3 who received Cerezyme treatment



Not actual patients.



2-year Gaucher Registry study

About the study: The 2-year ICGG Gaucher Registry study analyzed existing data from adult and pediatric patients with Gaucher disease type 3 who were treated with Cerezyme. The study measured Gaucher-related organ and blood problems as well as growth in patients with Gaucher disease type 3.

- Information entry is voluntary and not all the data on every parameter are available for every patient in the registry. The ICGG Registry includes patients with a variable range of disease status and management

In patients with Gaucher disease type 3, Cerezyme showed:



Improvements in average spleen and liver volume (compared to baseline)



Improvements in average red blood cell and platelet counts (compared to baseline)



Improvements in growth as measured by height Z-score (compared to baseline)

Important Safety Information (continued)

Common Side Effects:

- Common side effects reported in adults and children include back pain, chills, dizziness, fatigue, headache, allergic reactions, nausea, fever, and vomiting.

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Starting Cerezyme® (imiglucerase) for Injection

What to expect during treatment

- Cerezyme is given by intravenous (IV) infusion with dose and treatment frequency determined by your doctor. IV treatment with Cerezyme involves injecting the drug directly into your bloodstream through a vein
- Your doctor will determine your appropriate dose, frequency, and duration of the infusion based on your weight, disease severity, and how you respond to the infusion
- Cerezyme infusions may last 1 to 2 hours and may be administered from once every 2 weeks to up to 3 times a week. You will need ongoing appointments and tests to help doctors keep track of your progress

Cerezyme infusions can be completed in a variety of settings, such as a doctor's office, a treatment center, or, in some cases, at home.

During your infusion, you can do things like:



Read a book



Play a board game



Talk on your phone



Rest



Listen to music



Spend time with friends or family members

There may be potential side effects with Cerezyme. You should notify your doctor immediately if you experience any side effects while undergoing treatment with Cerezyme.

Starting Cerezyme® (imiglucerase) for Injection (continued)

Staying on treatment

Regular treatment with Cerezyme can help reduce or relieve some of the signs and symptoms of Gaucher disease type 1 or type 3. To continue benefiting from treatment, you will need to receive ongoing intravenous infusions—even though you may feel better at times. If therapy stops, symptoms may return or get worse.

Treatment-planning tips



If infusions need to occur during work or school hours, you may decide to inform employers, teachers, and others about the importance of regular infusions. This is an important decision and you may want to talk with your healthcare provider about it.



If you miss an infusion, talk to your doctor about rescheduling your appointment. It may be necessary for you to plan ahead if you will be moving or traveling, so that you don't miss an infusion.



If you are on Cerezyme and are pregnant or thinking about becoming pregnant, be sure to talk to your doctor. There may be risks associated with staying on Cerezyme during pregnancy. Be sure to tell your doctor if you are breastfeeding.



Treatment with Cerezyme does not mean you should stop all daily activities. If an opportunity arises for you to take a vacation, go camping, attend college, or make a permanent move, talk to your doctor about developing a plan for your treatment to potentially accommodate these changes.

Tests for progress

Regular tests will be required to check your progress and provide a way for your doctor to gain insight into the status of your disease and disease-management plan. Your doctor will decide which tests you need and how frequently you need them.

Because Gaucher disease is a progressive condition, sticking with your treatment plan is the best way to manage your health. Get the proper tests, stay on treatment, and ask for help from your support services when you need it.



Connected Care Throughout the Journey

CareConnect is a free, voluntary, and confidential support program for eligible patients and families living with lysosomal storage disorders such as Gaucher disease.



Connected Education:

Comprehensive disease education from diagnosis and beyond for individuals, families, and communities.



Connected Team:

Dedicated team who connects the dots between specialists, insurance, and appointments for a less fragmented care experience.



Connected Experience:

Programs designed to support you by connecting you with experts and the community to navigate life transitions and disease management.



Your experienced team is made up of two dynamic professionals:



Case Managers provide regional expertise in handling out-of-pocket costs and exploring options if you do not have insurance.



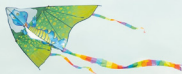
Patient Education Liaisons have a clinical background and provide in-person disease and treatment education.

If affording treatment is an issue, CareConnect may be able to help eligible patients access financial assistance.

CONNECT WITH US

www.careconnectpss.com
1-800-745-4447, option 3
info@CareConnectPSS.com






Cerezyme.
(imiglucerase) for injection

A LONG-STANDING COMMITMENT TO THE GAUCHER COMMUNITY

For more than 30 years, Sanofi has been committed to helping address the needs of people living with Gaucher disease and those who care for them.

As the pioneer of Gaucher disease type 1 treatment, Sanofi brings unmatched years of research, development, and patient data to its Gaucher disease program. Sanofi will continue to serve this community for years to come and remains committed to advancing Gaucher disease care through treatment options that address the range of patients' disease statuses and lifestyle demands.

Not actual patients.

Learn more about Gaucher disease type 1 and type 3 at [Cerezyme.com](https://www.cerezyme.com)

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