



*Marc, Margarita,
Jenna and Ivela,
family living with Fabry disease*

COUNT ON FABRAZYME®

The proven therapy for Fabry disease with over
20 years of real-world experience

Indication and Usage

Fabrazyme® is used to treat adults and children 2 years of age and older with confirmed Fabry disease.

Please see Important Safety Information on pages 29-31 and full Prescribing Information.


Fabrazyme®
agalsidase beta

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IMPORTANT SAFETY INFORMATION

YOUR GUIDE TO FABRY DISEASE AND FABRAZYME®

Taking charge of your health and managing your Fabry disease starts with you. Look to this guide for information on topics such as understanding your symptoms, preparing for treatment, and resources and support.

Fabry disease is a lifelong, genetic condition that typically becomes worse over time. It is important to prioritize your health and follow the management plan that your doctor has put together for you.

Fabrazyme has treated people with Fabry disease for more than 20 years and is the longest-studied Fabry disease therapy.

If you have any questions about Fabry disease or Fabrazyme, talk to your doctor or visit [Fabrazyme.com](https://www.fabrazyme.com).

Important Safety Information

Fabrazyme can cause serious side effects, including:

Severe Allergic (anaphylaxis) and Hypersensitivity Reactions

Approximately 1% of patients who have received Fabrazyme either during a clinical study or after Fabrazyme was approved have experienced anaphylactic (allergic) or severe hypersensitivity reactions during their infusion. Life-threatening severe anaphylactic (allergic) or severe hypersensitivity reactions have been seen in patients during Fabrazyme infusions.

Please see Important Safety Information on pages 29-31 and full **Prescribing Information**.


Fabrazyme®
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*Patricia, Ammeris,
and Shemary,
living with Fabry disease,
and their family*

About Fabry disease

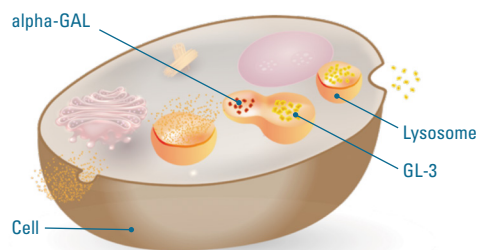
What is Fabry disease?

Fabry disease is an inherited condition caused by a change in one of your genes. Because of this change, also known as a variant, your body is unable to make enough of an enzyme called alpha-galactosidase A, or alpha-GAL. Enzymes are proteins that break down substances in your body. When enzymes don't work properly, substances build up and can cause diseases such as Fabry disease.

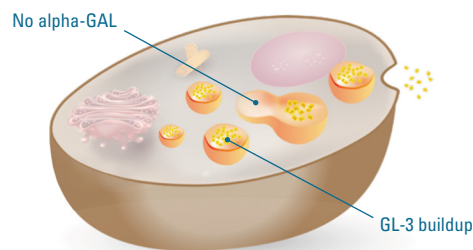
The role of alpha-GAL

Lysosomes in your cells have alpha-GAL to break down fats, such as globotriaosylceramide (globe-o-try-a-o-sill-ser-im-eyed), which is known as GL-3. When there's not enough functioning alpha-GAL in your body, GL-3 can't be broken down. Instead, GL-3 builds up in organs such as the kidneys, heart, skin, and brain, which can cause damage.

alpha-GAL breaks down and clears GL-3 buildup



GL-3 buildup with limited or no alpha-GAL



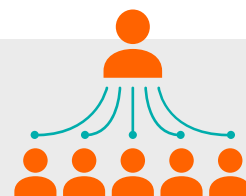
In people who don't have Fabry disease, lysosomes in the cells have **alpha-GAL that can break down and clear GL-3**.

In people with Fabry disease, **GL-3 builds up** in lysosomes and can't be broken down, so cells don't function as usual.

A **lysosome** is the digestive system of the cell, where fats and other substances are broken down.

Fabry disease and families

Fabry disease affects people of all ages and ethnic backgrounds. It is typically inherited, which means that parents with Fabry disease can pass it down to their children.



Fabry disease runs in families, and when one person is diagnosed, **an average of 5 additional relatives may also be affected.**

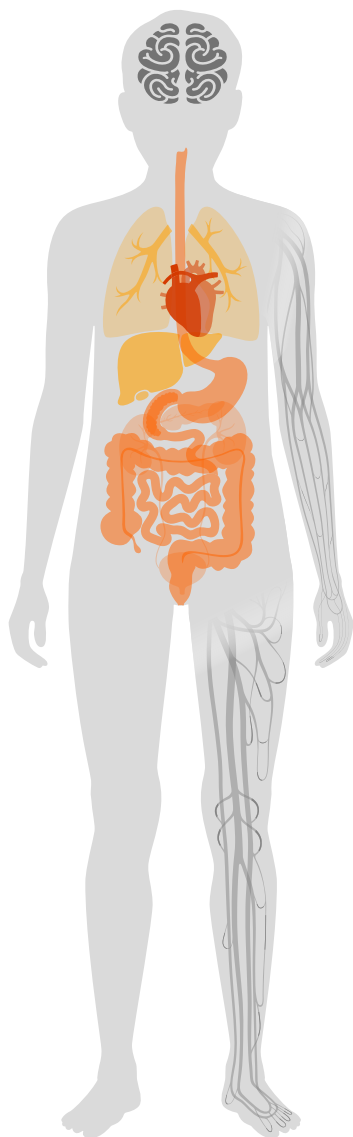
If someone in your family has Fabry disease, it's important to discuss testing options with your healthcare providers.



*Katie,
living with Fabry disease,
and her daughter Ali*

How Fabry disease can affect you

In people with Fabry disease, GL-3 starts to build up before birth and continues building up throughout life. Although everyone has GL-3, too much of it can cause damage to the body. Fabry disease affects women, men, and children differently. Even within the same family, people with Fabry disease may experience different symptoms including:



Head

- Strokes and ministrokes
- Starburst pattern in the eyes (corneal whorling)
- Headaches, lightheadedness, vertigo
- Hearing loss or ringing in the ears
- Breathing problems

Heart problems

- Chest pain
- Heart disease
- Enlarged heart
- Irregular heartbeat

Impaired kidney function

- Kidney failure
- Protein in urine

Stomach disorders

- Diarrhea
- Constipation
- Stomach cramping

Skin and nerve conditions

- Reddish or purple spots on skin
- Reduced ability to sweat
- Nerve pain in hands or feet
- Sensitivity to hot and cold temperatures

Please see Important Safety Information on pages 29-31 and full Prescribing Information.

Long-term effects of Fabry disease

Undiagnosed and unmanaged, Fabry disease can reduce life expectancy by approximately:

**5-14
YEARS
IN FEMALES**

**16
YEARS
IN MALES**

As a result of GL-3 buildup, people with Fabry disease are at risk for problems that may become life-threatening, such as kidney disease, heart problems, and early stroke. Some symptoms of Fabry disease may become worse over time without your knowledge.

It's important to track your symptoms and see your doctor regularly.

Tests to monitor Fabry disease

Your doctor will order certain tests to measure the function of your kidneys, heart, and brain to understand the effects of Fabry disease on your body. Tests can be performed as often as every six months or as infrequently as every three years, depending on your age and other factors. More frequent testing will be needed if you experience new or more severe symptoms, and when you start or change your treatment plan.

Some tests you may need:



Urine and blood tests



MRI scan



**Echocardiogram (echo),
ECG/EKG**

Please see page 27 for a full glossary of terms and their definitions.

It's important to go to all of your appointments so your doctor can monitor signs of Fabry disease. Even if you don't have any symptoms, test results can show if the disease is progressing silently.

When to start treatment

Because the symptoms of Fabry disease vary from person to person and not everyone has symptoms, you may wonder when you should start treatment.

To help guide your doctor, a panel of experts on Fabry disease has created treatment guidelines, which recommend that enzyme replacement therapy (ERT) should be considered in:

> Males and females with symptoms at time of diagnosis

- In published guidelines, Fabry disease experts recommend that ERT should be considered in males and females with symptoms at any age*

> Males and females without symptoms

- Males with “classic” gene variants starting at ages 8–10
- Males with “non-classic” gene variants and females without symptoms:
 - Should be monitored for the development of symptoms[†] that warrant treatment with ERT, such as problems in the kidneys, heart, or brain, as well as pain, gastrointestinal distress, difficulty sweating or exercise intolerance

*Classic and non-classic Fabry disease are defined in the Glossary on page 27

†Fabrazyme has not been studied in patients under the age of 2.

‡Fabrazyme has not been shown to affect symptoms of Fabry disease.

Important Safety Information (continued)

- These reactions included: swelling of the face, mouth and throat, narrowing of breathing airways, low blood pressure, hives, difficulty swallowing, rash, trouble breathing, flushing, chest discomfort, itching and nasal congestion.
- People who have experienced these reactions have required treatment including heart/lung resuscitation, oxygen, fluids given through a vein, hospitalization, and treatment with inhaled drugs called beta-adrenergic agonists to help open the breathing airways, antihistamines, epinephrine (also known as adrenaline), and a medication given through the vein called a corticosteroid (or steroid) which helps to decrease the body’s allergic reaction by decreasing inflammation.



*Tony and Tonia,
living with Fabry disease*



Talk with your doctor to understand how treatment can help you manage your Fabry disease.

Please see Important Safety Information on pages 29-31 and full Prescribing Information.



Ammeris and Patricia,
living with Fabry disease

On your Fabry disease journey,

COUNT ON FABRAZYME®

Fabrazyme can be prescribed for people with Fabry disease, regardless of disease severity, enzyme activity, or type of genetic variant.

Indication

Fabrazyme® is used to treat adults and children 2 years of age and older with confirmed Fabry disease.

Fabrazyme is FIRST FOR FABRY



FIRST Prescribed Treatment:

#1 prescribed, FDA-approved treatment for Fabry patients 2 years and up, regardless of genetic variant. Fabrazyme can be used for all genders or disease severity.⁴



FIRST in Evidence:

First to demonstrate long-term, real-world efficacy and safety data.^{4,5}



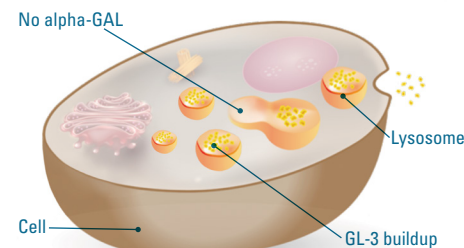
FIRST for Patients:

Acting first for the Fabry community with a 20+ year commitment to supporting patients at every step of their journey⁷

Fabrazyme helps clear GL-3 buildup by replacing the missing enzyme in Fabry disease

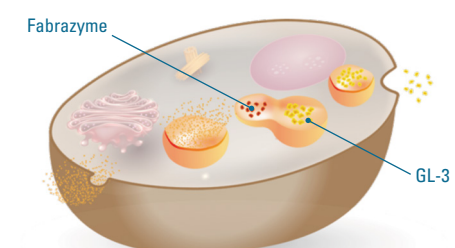
Fabrazyme is an ERT that provides the enzyme that's missing or deficient. The fully functional enzyme helps clear GL-3 in your cells.

GL-3 buildup without Fabrazyme



The alpha-GAL enzyme is missing or not working, so **GL-3 builds up** in cells, causing damage.

Fabrazyme breaks down and clears GL-3 buildup



Fabrazyme replaces the missing enzyme, **breaking down and clearing GL-3 buildup** in certain cells.

Important Safety Information (continued)

- If you experience a severe allergic or anaphylactic reaction, your healthcare professional will immediately stop the infusion of Fabrazyme and provide you the necessary emergency medical treatment. Because of the possibility that severe hypersensitivity reactions may occur, appropriate medical support should be available during your Fabrazyme infusion.

Please see Important Safety Information on pages 29-31 and full Prescribing Information.

1. Data on file



FIRST FOR FABRY

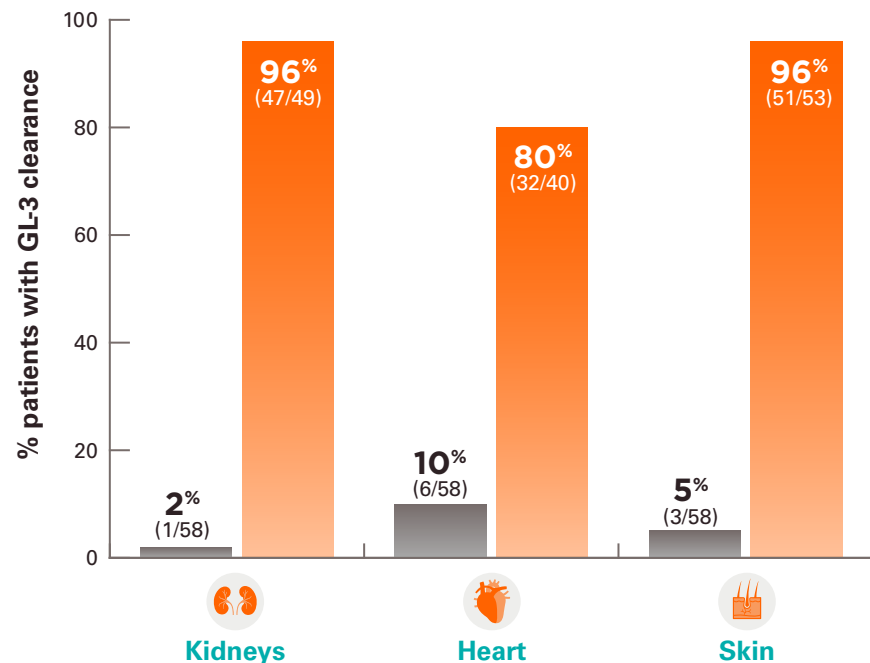
FABRAZYME®
(agalsidase beta)

In clinical trials, Fabrazyme® was proven to clear GL-3 buildup

After 5 months of treatment with Fabrazyme in **Study 1**, most patients achieved GL-3 clearance resulting in trace, or nearly none, GL-3 inclusions in certain cells of their: **Kidneys:** 69% (20/29) of Fabrazyme patients compared with 0% (0/29) of placebo patients; **Heart:** 72% (21/29) of Fabrazyme patients compared with 3% (1/29) of placebo patients; **Skin:** 100% (29/29) of Fabrazyme patients compared with 3% (1/29) of placebo patients.

Patients treated with Fabrazyme who had GL-3 clearance at 6 months in the Study 1 extension

■ Fabrazyme
■ Before treatment



Study 1 design: This study included 58 Fabry patients ages 16-61. Patients in this study received either Fabrazyme or placebo every 2 weeks for 5 months. Patients received a score of 0 to 3 based on the amount of GL-3 in their cells. Most people received a score of 0, meaning the GL-3 in their cells was nearly none or trace amounts.

Study 1 extension design: All 58 patients who completed Study 1 were treated with Fabrazyme every two weeks in an open-label extension study.

In an extension study, patients who regularly received Fabrazyme for up to 5 years maintained normal GL-3 levels in their blood.

Marc,
living with
Fabry disease

Similar long-term GL-3 clearance was achieved at 4.5 years in the majority of patients taking Fabrazyme in this extension study.*

*In the extension study, patients had sustained GL-3 clearance in certain cells of the kidneys (100%; 8/8) and heart (75%; 6/8) at 4.5 years.

Important Safety Information (continued)

In the clinical studies, some patients developed IgE antibodies or a reaction to an allergy skin test specific to Fabrazyme. IgE antibodies are a specific kind of antibody that can sometimes be produced by the body's immune system during an allergic reaction.

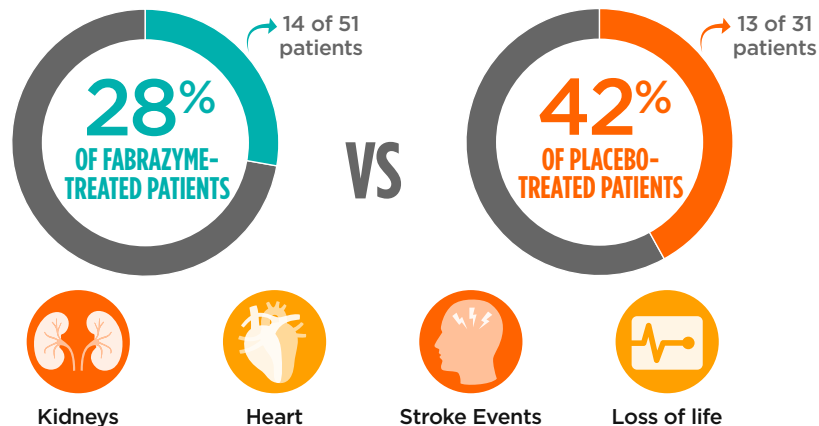
- Higher amounts of hypersensitivity reactions were seen in adult patients whose immune systems repeatedly made anti-Fabrazyme antibodies and in patients who had high antibody titers (units used to measure how much anti-drug-antibody your immune system is making) compared to adult patients with negative antibody titers.

Please see Important Safety Information on pages 29-31 and full Prescribing Information.

A smaller percentage of individuals treated with Fabrazyme® experienced a clinically significant event*

A clinically significant event is defined as the first instance in any of the four categories below, which occurred after the study started.

A smaller percentage of people had heart, kidney, stroke events, or death



Study design: A randomized, double-blind, placebo-controlled, multinational, multicenter study of 82 patients (72 males and 10 females) with Fabry disease. Patients were 20 to 72 years of age with a median age of 45 years at baseline, a median age of 36 years at Fabry disease diagnosis, and at a median of 10 years at symptom onset.

*Renal, cardiac, or stroke events, or death.

Important Safety Information (continued)

- Your doctor should consider testing for IgE antibodies if you experience suspected allergic reactions. Providing Fabrazyme to patients who have experienced severe or serious allergic reactions to Fabrazyme should only be done after carefully considering the risks and benefits of continuing the treatment, and only under the direct supervision of a qualified healthcare professional and with appropriate medical support readily available.



Fabrazyme is the only ERT indicated for patients 2 years of age and older that has proven long-term efficacy and safety.



Tony, Tonia, and Katie
living with Fabry disease

Please see Important Safety Information on pages 29-31 and full Prescribing Information.

Fabrazyme®
agalsidase beta

FIRST FOR FABRY

In children with Fabry disease aged 2-7 years, Fabrazyme® normalized GL-3 in the blood

An analysis of 24 children with elevated plasma GL-3 levels (ie, >7.03 µg/mL), taking Fabrazyme showed normalization of GL-3 levels in 91% (20/22), 95% (18/19), and 92% (12/13) of patients at 6, 12, and 24 months of treatment, respectively.

Study overview: In an observational study of 24 pediatric patients ages 2 to 7, normalization of plasma GL-3 was observed.



The overall safety profile was similar between the pediatric and the adult population.

Important Safety Information (continued)

Infusion-Associated Reactions

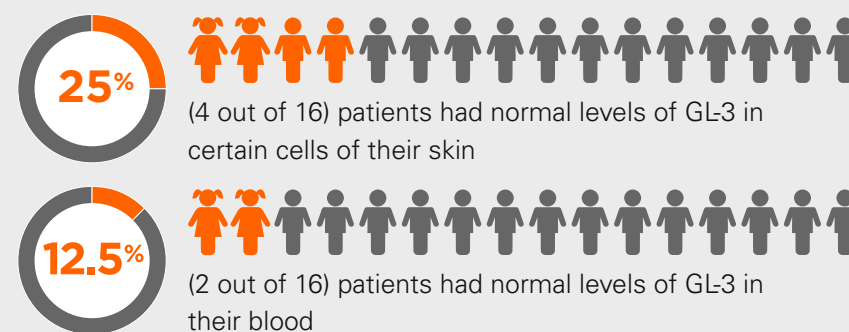
In clinical studies with Fabrazyme, 59% of patients experienced infusion-associated reactions during Fabrazyme administration, some of which were severe. Infusion-associated reactions are defined as adverse reactions occurring on the same day as your infusion. During the clinical trials, infusion-associated reactions occurred more frequently in patients who were positive for anti-Fabrazyme antibodies than in patients who did not have anti-Fabrazyme antibodies.

Please see Important Safety Information on pages 29-31 and full [Prescribing Information](#).

In children 8 years and older, Fabrazyme cleared GL-3

Study overview: 16 pediatric patients with Fabry disease, aged 8-16 years, were evaluated in an open-label, uncontrolled study.

Before treatment with Fabrazyme



After 5.5 months and 11 months of Fabrazyme treatment



Boy Girl Had GL-3 buildup Had GL-3 clearance

The most common adverse reactions (>20%) in patients aged 8-16 were headache, abdominal pain, sore throat, fever, nausea, vomiting, nasal inflammation, diarrhea, joint pain, and dizziness.

The rate of kidney function decline was studied in Fabrazyme[®]-treated individuals

One of the ways your doctor measures your kidney function is by monitoring your eGFR—a calculation made using a blood test. eGFR represents an estimation of how much fluid (mL) is filtered by the kidneys over time (min) based on your age, body size, and sex (represented by 1.73m²). eGFR slope is a measurement of kidney function over time, and is reported as a change in mL/min/1.73m²/year. A declining eGFR may indicate a decline in kidney function.

1.7
mL/MIN/1.73M²/YEAR

**estimated difference
in the rate of kidney
function decline**

The rate of renal function decline was assessed in Fabry disease patients aged ≥ 16 years. The mean slope of eGFR* was -1.5 mL/min/1.73m²/year in the Fabrazyme-treated group and -3.2 mL/min/1.73m²/year in the untreated group. The mean difference in eGFR between the two groups was 1.7 mL/min/1.73m²/year.

Study design: In a long-term observational study, the rate of decline in renal function (eGFR slope) was assessed in 122 patients with Fabry disease aged 16 years and older treated with Fabrazyme and matched to a historical cohort of untreated patients.

Talk to your doctor about what this may mean for you.



*Ammeris,
living with Fabry disease,
and her family*

Important Safety Information (continued)

- For patients who have had reactions to their infusions, it is recommended that they be given anti-fever and antihistamine medications right before their next infusions. Infusion-associated reactions have happened in some patients even after taking these medications before their infusions.
- If an infusion-associated reaction occurs, slowing the infusion rate, stopping the infusion for a short time and/or giving more anti-fever and antihistamine medications and or steroids may improve the symptoms.
- If severe infusion-associated reactions happen, your healthcare professional should consider stopping the Fabrazyme infusion right away and should provide medical care for your condition. Severe reactions are generally managed by giving antihistamine medications, corticosteroids, fluids through the vein, and/or oxygen when needed. Because severe infusion-associated reactions may happen, medical treatment should be readily available during your Fabrazyme infusion.
- People with advanced Fabry disease may have heart problems which could put them at a higher risk for severe complications from infusion-associated reactions. These patients should be watched closely during their infusion if the decision is made to give them Fabrazyme.


Fabrazyme[®]
agalsidase beta

FIRST FOR FABRY

Please see Important Safety Information on pages 29-31 and full **Prescribing Information**.

The safety of Fabrazyme[®] has been assessed in several studies*

What are the most common side effects of Fabrazyme?

In clinical trials, common side effects that occurred in 20% or more of people treated with Fabrazyme and in more than 2.5% of people who received placebo, include:

Side effect	Fabrazyme (n=80)	Placebo (n=60)
Upper respiratory tract infection	53%	42%
Chills	49%	13%
Fever (pyrexia)	39%	22%
Headache	39%	28%
Cough	33%	25%
Burning or tingling in hands and feet (paresthesia)	31%	18%
Fatigue	24%	17%
Swelling in the limbs (peripheral edema)	21%	7%
Dizziness	21%	8%
Rash	20%	10%

n=Number of patients.

*The safety of Fabrazyme has been assessed in 4 clinical studies involving 162 people with Fabry disease.

Talk to your doctor about any side effects you experience when taking Fabrazyme. Your doctor can help manage infusion-associated reactions or other side effects.



Patricia,
living with Fabry disease,
and her grandson

Serious side effects

- Life-threatening severe anaphylactic (allergic) or severe hypersensitivity reactions have been seen in patients during Fabrazyme infusions.
- Approximately 1% of patients who have received Fabrazyme either during a clinical study or after Fabrazyme was approved have experienced anaphylactic (allergic) or severe hypersensitivity reactions during their infusion.
- In clinical studies, 59% of patients experienced infusion-associated reactions during Fabrazyme treatment, some of which were severe.
- During the clinical trials, infusion-associated reactions occurred more frequently in patients who were positive for anti-Fabrazyme antibodies than in patients who did not have anti-Fabrazyme antibodies.
- People with advanced Fabry disease may have heart problems which could put them at a higher risk for severe complications from infusion-associated reactions. These patients should be watched closely during their infusion if the decision is made to give them Fabrazyme.

Please see Important Safety Information on pages 29-31 and full Prescribing Information.



*Bordelon-Lee Family,
living with Fabry disease*

Treatment with Fabrazyme®

Fabrazyme can be given in a number of treatment settings, including:



Hospital



Doctors' office



Infusion center



Home

Talk to your doctor about which treatment setting is right for you.

Important Safety Information (continued)

Common and Other Possible Side Effects: Common side effects reported in 20% or more of Fabrazyme treated patients in clinical studies compared to placebo were upper respiratory tract infection, chills, fever, headache, cough, burning and/or tingling sensation, fatigue, swelling in the legs, dizziness and rash.

Make your treatments a priority

Fabrazyme is an infusion that's given to help prevent the buildup of GL-3. Fabrazyme keeps helping to clear GL-3 as long as you continue treatment.



Follow the Fabrazyme treatment plan prescribed by your doctor, even if you're not feeling sick.

Please see Important Safety Information on pages 29-31 and full Prescribing Information.



FIRST FOR FABRY

CareConnectPSS[®]

Personalized Support Services

CareConnectPSS[®], personalized support services for patients, represents Sanofi more than 35-year commitment to supporting the rare disease community. CareConnectPSS is designed to support each patient's unique journey.

Our range of support to help patients living with a rare disease includes:



Programs such as the Copay Assistance Program and Patient Assistance Program for eligible patients*



Disease-specific information, including information on how rare diseases may run in families



Care coordination for treatment



Dedicated CareConnectPSS Patient Education Liaisons and Case Managers



Your **Patient Education Liaison** can help educate you, your family, friends, teachers, or employers about Fabry disease.



Your **Case Manager** will guide you through every step of the journey. They can provide resources that may help you with out-of-pocket costs, as well as health insurance claims and billing.



Margarita,
living with Fabry disease

Sanofi acts first for patients.
Connect with us online at [CareConnectPSS.com](https://www.CareConnectPSS.com)

Questions about the support services that are available to you? Contact a case manager at info@CareConnectPSS.com or 1-800-745-4447, option 3.

Please see Important Safety Information on pages 29-31 and full Prescribing Information.

*Patients whose medication or infusion-related costs are covered by a state or federal health care program, including but not limited to Medicare, Medicare Part D, Medicaid, Veterans Affairs (VA), Department of Defense (DoD), or TRICARE, are not eligible for the Co-Pay Program. Patients must live in the US or a US territory. Patients must be eligible under applicable state law(s). Other terms and conditions of the Program apply. Co-Pay Program does not cover or provide support for MD office visits/evaluations, nursing services/observation periods, blood work, x-rays or other testing, pre-medications/other medications, transportation or other related services associated with treatment. In accordance with state law, infusion-related costs are not covered for commercially insured patients residing in MA or RI. Sanofi reserves the right to modify or discontinue the programs at any time without notice. Savings may vary depending on patients' out-of-pocket costs. All program details provided upon registration.

Fabry disease resources

This listing is provided as a resource only and does not constitute an endorsement by Sanofi of any particular organization or its programming. Additional resources on this topic may be available and should be investigated. Sanofi does not review or control the content of non-Sanofi websites. These listings do not constitute an endorsement by Sanofi of information provided by any other organizations.

Fabry Disease Information | discoverfabry.com

A website created by Sanofi with information about Fabry disease

Fabry Registry | registrynxt.com

A program designed to help doctors better understand Fabry disease

Fabry Support & Information Group (FSIG) | fabry.org

A nonprofit organization dedicated to raising awareness and providing support to you and caregivers of patients with Fabry disease

Genetic Alliance | geneticalliance.org

The world's leading nonprofit health advocacy organization committed to transforming health through genetics

National Fabry Disease Foundation (NFDF) | fabrydisease.org

This foundation supports the Fabry disease community through education, assistance, identification, research, and advocacy

National Organization for Rare Disorders (NORD) | rarediseases.org/rare-diseases/fabry-disease

A nonprofit federation of health organizations dedicated to helping people with rare, or "orphan," diseases and assisting the organizations that serve them

National Society of Genetic Counselors (NSGC) | nsgc.org

An organization that will help you find a genetic counselor who is in your area or available by phone

American Kidney Fund (AKF) | kidneyfund.org/all-about-kidneys/other-kidney-diseases/fabry-disease

A non-profit organization that provides comprehensive programs of kidney health awareness, education, and prevention.

National Kidney Fund | kidney.org/atoz/content/fabry

A nonprofit that is a lifeline for all people affected by kidney disease with an emphasis on enhancing lives through action, education and accelerating change.

Please see Important Safety Information on pages 29-31 and full Prescribing Information.

Glossary

alpha-galactosidase A (alpha-ga-lack-tose-i-daze A) (alpha-GAL): An enzyme that is missing, not working properly, or present in smaller-than-normal amounts in people with Fabry disease. It is normally found in the lysosomes.

classic Fabry disease: A type of Fabry disease in which there is little or no functional alpha-GAL activity. Symptoms typically begin in childhood and adolescence.

dialysis: A treatment for kidney failure that purifies your blood as a substitute for the normal function of your kidneys.

ECG/EKG: An electrocardiogram, which measures electrical activity of the heart.

echo: An echocardiogram, which is an ultrasound of the heart.

enzyme: A protein produced by the body that acts to chemically change other substances. Enzymes are involved in breaking down or chemically altering substances so that the body can use or get rid of them.

eGFR: Estimated glomerular filtration rate is a measure of kidney function and can be used to determine your stage of kidney disease.

Fabry disease: A genetic disorder caused by a deficiency of the enzyme alpha-galactosidase A.

gene: A piece of DNA that codes for a particular protein. Each gene occupies a specific location on a chromosome, which defines a person's bodily makeup and function.

gene variant: A change in one of your genes.

genetic: Affecting or affected by genes.

globotriaosylceramide (globe-o-try-a-o-sill-ser-im-eyed): A type of fat (also known as GL-3) that accumulates in the blood vessel walls of people with Fabry disease as a result of a deficiency in alpha-galactosidase A.

GL-3: An abbreviation for globotriaosylceramide.

infusion: The delivery of liquid medicine into the blood through a vein.

kidney disease: A condition in which the kidneys are damaged and can't filter blood normally.

lysosome: A small structure in most cells that acts as the digestive system of the cell. Lysosomes contain and make various enzymes that break down substances. In Fabry disease, GL-3 builds up in the lysosomes.

non-classic Fabry disease: Also referred to as late-onset or atypical Fabry disease, is a type of the disease in which symptoms are generally less severe and may be limited to a single organ.

placebo: An inactive substance used in clinical trials for comparison to help researchers understand clinical study results.

TIA: A transient ischemic attack, sometimes called a "ministroke," is caused by a clot or blockage to the brain. The symptoms usually last a short time, with the blockage dissolving by itself.



Marc and Ivela,
living with Fabry disease

Learn more at
Fabrazyme.com

Important Safety Information

Indication and Usage

Fabrazyme® is used to treat adults and children 2 years of age and older with confirmed Fabry disease.

Important Safety Information

Fabrazyme can cause serious side effects, including:

Severe Allergic (anaphylaxis) and Hypersensitivity Reactions

Approximately 1% of patients who have received Fabrazyme either during a clinical study or after Fabrazyme was approved have experienced anaphylactic (allergic) or severe hypersensitivity reactions during their infusion. Life-threatening severe anaphylactic (allergic) or severe hypersensitivity reactions have been seen in patients during Fabrazyme infusions.

- These reactions included: swelling of the face, mouth and throat, narrowing of breathing airways, low blood pressure, hives, difficulty swallowing, rash, trouble breathing, flushing, chest discomfort, itching and nasal congestion.
- People who have experienced these reactions have required treatment including heart/lung resuscitation, oxygen, fluids given through a vein, hospitalization, and treatment with inhaled drugs called beta-adrenergic agonists to help open the breathing airways, antihistamines, epinephrine (also known as adrenaline), and a medication given through the vein called a corticosteroid (or steroid) which helps to decrease the body's allergic reaction by decreasing inflammation.
- If you experience a severe allergic or anaphylactic reaction, your healthcare professional will immediately stop the infusion of Fabrazyme and provide you the necessary emergency medical treatment. Because of the possibility that severe hypersensitivity reactions may occur, appropriate medical support should be available during your Fabrazyme infusion.

Continued on next page

Please see Important Safety Information on pages 29-31 and full Prescribing Information.


Fabrazyme®
agalsidase beta

FIRST FOR FABRY

Important Safety Information, continued

In the clinical studies, some patients developed IgE antibodies or a reaction to an allergy skin test specific to Fabrazyme. IgE antibodies are a specific kind of antibody that can sometimes be produced by the body's immune system during an allergic reaction.

- Higher amounts of hypersensitivity reactions were seen in adult patients whose immune systems repeatedly made anti-Fabrazyme antibodies and in patients who had high antibody titers (units used to measure how much anti-drug-antibody your immune system is making) compared to adult patients with negative antibody titers.
- Your doctor should consider testing for IgE antibodies if you experience suspected allergic reactions. Providing Fabrazyme to patients who have experienced severe or serious allergic reactions to Fabrazyme should only be done after carefully considering the risks and benefits of continuing the treatment, and only under the direct supervision of a qualified healthcare professional and with appropriate medical support readily available.

Infusion-Associated Reactions

In clinical studies with Fabrazyme, 59% of patients experienced infusion-associated reactions during Fabrazyme administration, some of which were severe. Infusion-associated reactions are defined as adverse reactions occurring on the same day as your infusion. During the clinical trials, infusion-associated reactions occurred more frequently in patients who were positive for anti-Fabrazyme antibodies than in patients who did not have anti-Fabrazyme antibodies.

- For patients who have had reactions to their infusions, it is recommended that they be given anti-fever and antihistamine medications right before their next infusions. Infusion-associated reactions have happened in some patients even after taking these medications before their infusions.
- If an infusion-associated reaction occurs, slowing the infusion rate, stopping the infusion for a short time and/or giving more anti-fever and antihistamine medications and or steroids may improve the symptoms.

- If severe infusion-associated reactions happen, your healthcare professional should consider stopping the Fabrazyme infusion right away and should provide medical care for your condition. Severe reactions are generally managed by giving antihistamine medications, corticosteroids, fluids through the vein, and/or oxygen when needed. Because severe infusion-associated reactions may happen, medical treatment should be readily available during your Fabrazyme infusion.
- People with advanced Fabry disease may have heart problems which could put them at a higher risk for severe complications from infusion-associated reactions. These patients should be watched closely during their infusion if the decision is made to give them Fabrazyme.

Common and Other Possible Side Effects: Common side effects reported in 20% or more of Fabrazyme treated patients in clinical studies compared to placebo were upper respiratory tract infection, chills, fever, headache, cough, burning and/or tingling sensation, fatigue, swelling in the legs, dizziness and rash.



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Sanofi does not provide medical advice, diagnosis, or treatment. The health information contained herein is provided for general educational purposes only. Your healthcare professional is the best source of information regarding your health. Please consult your healthcare professional if you have any questions about your health or treatment.

Indication and Usage

Intended for U.S. Residents Only

Fabrazyme® is used to treat adults and children 2 years of age and older with confirmed Fabry disease.

Please see Important Safety Information on pages 29-31 and full Prescribing Information.

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