ELFABRIO®
(pegunigalsidase alfa-iwxj)

For adults with **Fabry disease**

Picture what long-lasting treatment can do*

Elfabrio has been shown to work safely and effectively over the long term.†
And with a long half-life, Elfabrio can last for a long time in your body.

*Elfabrio has an initial half-life of 78.9 ± 10.3 hours. Clinical studies have not shown that a long half-life results in a medicine working better or more safely. Infusions are every 2 weeks.
†Trials within the Full Prescribing Information extend up to 2 years. Results from a 6-year study were published in a medical journal.

Indication

Elfabrio® (pegunigalsidase alfa-iwxj) is a prescription infusion medicine used to treat adults with confirmed Fabry disease.

Important Safety Information

What is the most important information I should know about Elfabrio?

Severe allergic reactions (hypersensitivity reactions), including anaphylaxis, may occur during and after Elfabrio treatment. If severe allergic reactions or anaphylaxis occurs during treatment, your healthcare provider will immediately stop the infusion and provide appropriate medical care. If these reactions should occur after treatment, seek immediate medical care.

Please see additional Important Safety Information throughout and accompanying Full Prescribing Information, including Boxed Warning.

What is Fabry disease?

Fabry disease is a chronic, progressive genetic disease, caused by changes in genes that express alpha-galactosidase A (or alpha-Gal A), an enzyme that helps to break down a type of fat in the body. Buildup of this fat causes the symptoms associated with Fabry.

Fabry disease doesn't go away on its own, or with treatment, and it may get worse over time.

What does Fabry do to your body?

Fabry affects everyone differently. There are a lot of different symptoms in different parts of the body (see page 4 for a list). It could be easy to overlook some of the less serious symptoms of Fabry because they are often associated with other conditions. But when seen together, your doctor may begin to suspect an underlying condition, like Fabry.

Fabry disease is a multisystemic disorder, meaning it can affect many of the body's organs and areas of the body. It is important to seek diagnosis and treatment before Fabry progresses too far. When symptoms become serious, this can mean organ damage has already begun.

Who is affected by Fabry?

Both males and females can have Fabry.

Symptoms can set in at different times, from childhood into adulthood.

Men living with Fabry tend to have symptoms earlier and more severe disease. This has contributed to the misconception that women are only carriers of Fabry and can't experience symptoms—but that's just not true.

70% of women diagnosed with Fabry experience symptoms. The other 30% may not, but can still pass Fabry disease to their children.

How rare is rare?

1 in 15,000

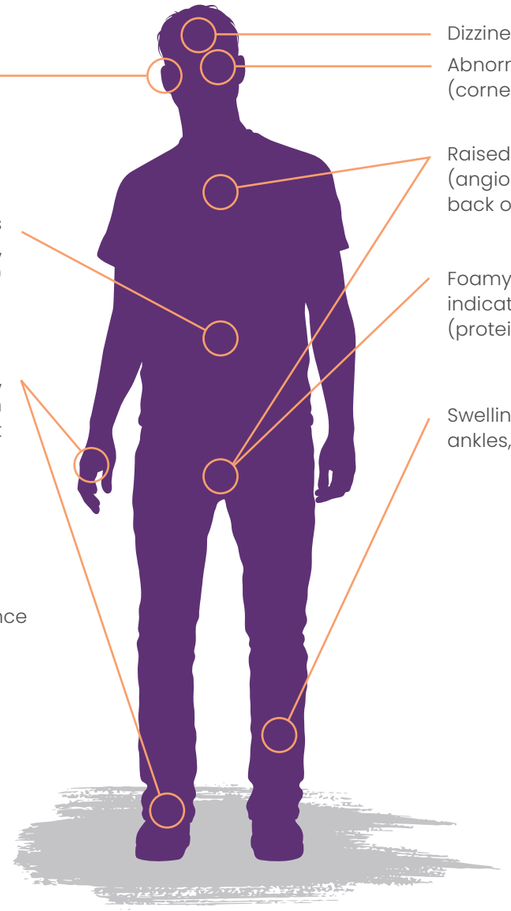
worldwide are thought to have Fabry at birth, but due to underdiagnosis it may be even more common

<5,000 Americans

are known to have Fabry disease according to the NIH. *Many more are undiagnosed*

NIH, National Institutes of Health.

Look out for the symptoms



General symptoms:

- Extreme pain during physical activity
- Heat or cold intolerance
- Flu-like symptoms (fatigue, fever, body aches)
- Sweating less (hypohidrosis) or not at all (anhidrosis)

Seek treatment to help prevent organ damage

Kidney failure

Heart problems, including arrhythmia, heart attacks, enlarged heart, and heart failure

Nerve damage (peripheral neuropathy)

Strokes, including mini strokes, also known as transient ischemic attacks (TIA)

What types of doctors will I need to see?

Your care team may consist of a mix of different specialists and healthcare providers, depending on the signs and symptoms you experience and which organs are affected.

Primary care doctor

Monitors your overall health. If you aren't sure which specialist to talk to, your primary care doctor will be able to help

Geneticist

Helps diagnose Fabry in you and other family members. In some cases, they also may serve as your primary care coordinator

Additional specialists

Depending on your symptoms, you may see an ENT, a hearing specialist, or any of the following:

A **neurologist** may keep track of symptoms related to your nervous system

A **cardiologist** may monitor your heart function, which includes heart structure and heart rhythm

A **nephrologist** may monitor how well your kidneys are working and order certain lab tests of your urine and blood

An **ophthalmologist or optometrist** may aid in diagnosis by recognizing distinctive patterns in your eyes. Regular follow-ups are important as well

A **gastroenterologist** may help address any issues you are experiencing that affect your digestion or impact bowel movements

Don't forget about your mental health

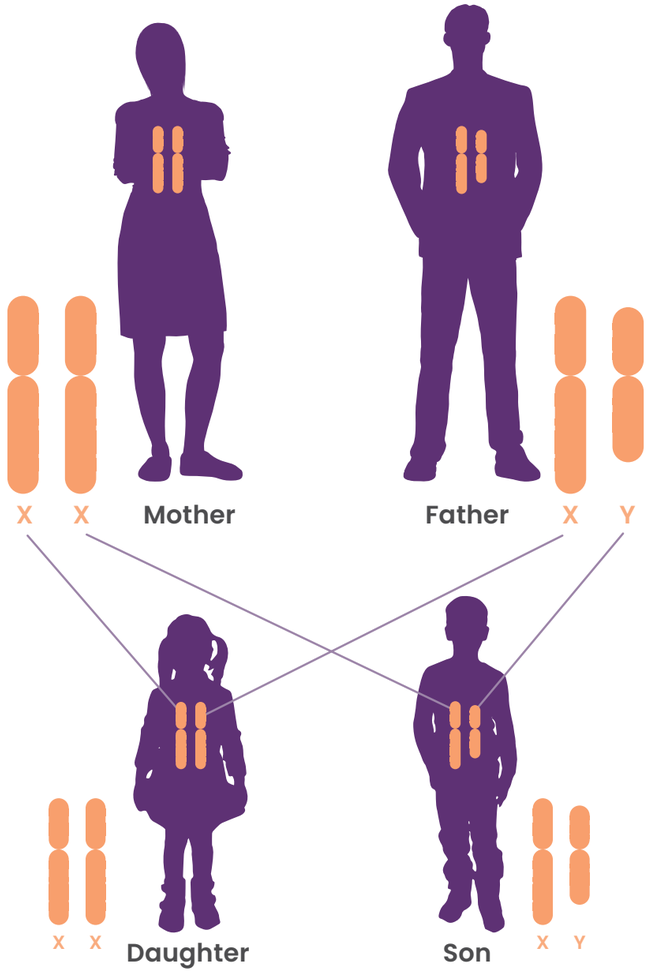
A **psychologist** may help, as Fabry doesn't just affect your physical abilities; it can also make you feel:

- Anxious or have panic attacks
- Isolated or lonely
- Fear or guilt of having a disease that can be passed down
- Depressed
- That friendships are affected

ENT, ear, nose, and throat doctor.

How is Fabry inherited?

Fabry disease is inherited as a variant on the X chromosome, so it is considered an X-linked disorder. This means the genetic variant can be passed down from either fathers or mothers, but the likelihood is different depending on which parent has the genetic variant. That's because females have two X chromosomes. Males have only one.



In females, Fabry disease may also be associated with a randomly occurring genetic variation called X-inactivation (which silences one of the X chromosomes).

Ruling out the possibility of having Fabry is recommended in families where someone is affected.

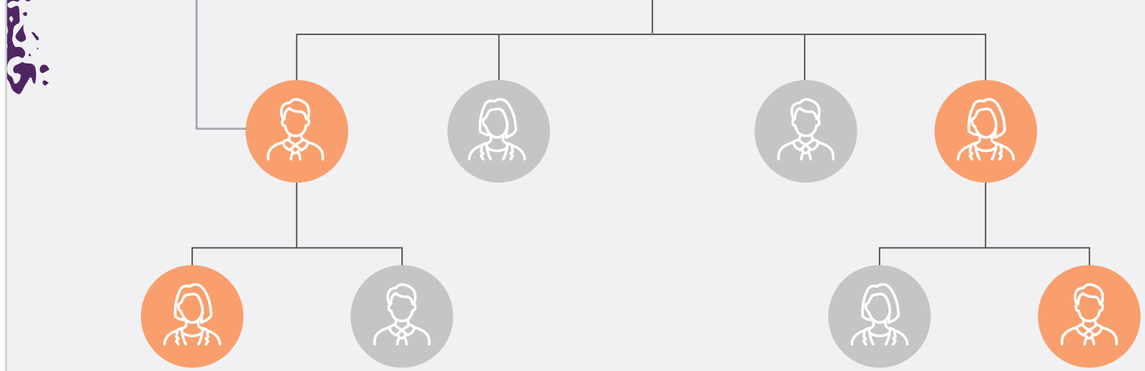
What are the odds of passing down the Fabry gene?

Your likelihood of inheriting Fabry depends on your family's genes. Fabry disease is not always passed on to the next generation. However, with any diagnosis of Fabry, studies show that other members of the family are at risk.

An example of a Fabry family tree

A Father's Gene
The Fabry gene is only passed on the X chromosome, which means it is passed to all daughters. However, sons are unaffected because they always receive the Y chromosome.

A Mother's Gene
The Fabry gene can be passed to both males and females, as the gene sits on the X chromosome. Because a female has two Xs, there's a 50% chance of passing down the Fabry gene.



Affected
Has inherited the Fabry gene variant

Unaffected
Has not inherited the Fabry gene variant

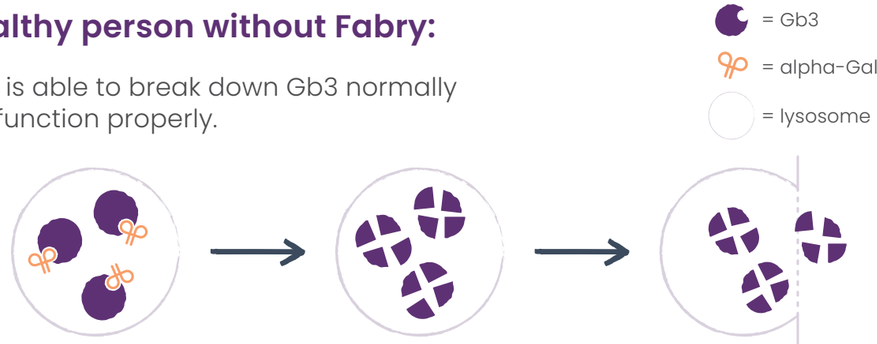
What happens in Fabry?

Enzymes help the cells in our bodies to work properly. The enzyme alpha-Gal A works in a part of the cell called a lysosome. There it breaks down and removes a type of fat known as globotriaosylceramide (or Gb3). This process helps cells function as they should.

People with Fabry may either have reduced or no alpha-Gal A enzymes. In some genetic variants, alpha-Gal A may not be working properly. As a result, Gb3 builds up until it damages the lysosome and the cell. This Gb3 buildup will gradually affect the body's tissues and, if left untreated, damage essential organs.

In a healthy person without Fabry:

The body is able to break down Gb3 normally and can function properly.



There is enough alpha-Gal A enzymes to address the Gb3.

Alpha-Gal A breaks down Gb3.

Once broken down, the Gb3 can pass through the lysosome wall normally.

In people with Fabry:

Alpha-Gal A is not working properly, or there is not enough of it or none at all. Classic Fabry disease typically has no or very little alpha-Gal A produced.

There is not enough working alpha-Gal A to address all the Gb3.

Without getting broken down, Gb3 can't escape the lysosome.

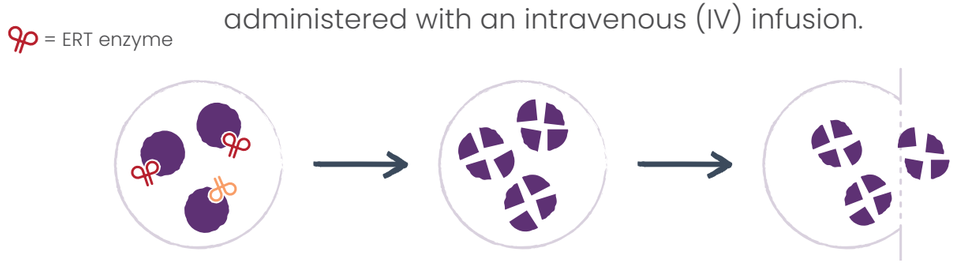
Gb3 builds up in the lysosome, damaging the cells. This is thought to cause the symptoms.

How is Fabry treated?

There are 2 available options for the treatment of Fabry disease, ERT or chaperone therapy.

Enzyme replacement therapy (ERT)

ERT is an option for any person living with Fabry, administered with an intravenous (IV) infusion.



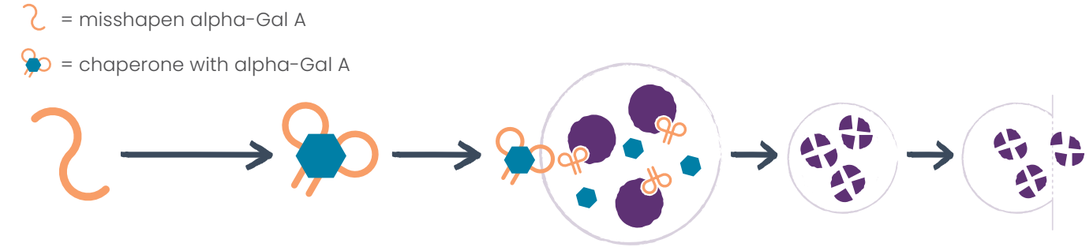
An ERT increases the amount of working alpha-Gal A enzyme.

The body now has more alpha-Gal A to break down the Gb3 buildup inside the lysosome.

Once broken down, Gb3 can pass through the lysosome wall as expected.

Chaperone therapy

This is an oral option only for people with certain types of genetic variants. In these variants the alpha-Gal A is not shaped correctly, so the body cannot use it.



Alpha-Gal A is misshaped and not functional.

This medicine binds to the misshapen alpha-Gal A and changes its shape so the enzyme can move into the lysosome.

Once inside the lysosome, the chaperone separates and the enzyme can work.

Gb3 is then broken down.

Once broken down, Gb3 can pass through the lysosome wall as expected.

Starting treatment as soon as possible can increase your chances of managing Fabry symptoms, slowing down disease progression, and preventing organ damage.

Managing life with Fabry

Because Fabry is a chronic illness, you'll need to make sure to prioritize yourself and your health. Regular check-ins with your healthcare team are important.

Routine follow-ups for people living with Fabry

Formal tests

Magnetic resonance imaging (MRI) of the brain and sometimes the heart

Echocardiogram (echo) or electrocardiogram (EKG/ECG) to assess heart function

Your provider may order other tests

Blood & urine tests

Kidney function is monitored through a measure called estimated glomerular filtration rate (eGFR)

Gb3 and/or lyso-Gb3 levels (fat buildup) in the cells are monitored through blood tests

Anti-drug antibodies (ADAs) are monitored to see if your immune system is reacting to your treatment, which could impact your results

Identifying ADAs

ADAs may develop when your immune system reacts to a drug, causing your body to produce antibodies against ("anti") the drug.

- ADAs may negatively affect how well and how safely a drug works
- Your provider may monitor ADAs (for example, every 3-6 months) to ensure your treatment continues to work

Monitoring Fabry and your treatment

Tracking treatment

Your medical team may monitor how your body is functioning on treatment as well as your pain levels.

Your healthcare provider may ask the following questions:

- Do you feel like your symptoms tend to increase in between infusions?
- Do you believe the treatment is working as effectively as when you started?
- Are you experiencing any side effects or infusion reactions from treatment?
- Is your life affected by infusion times and premedications (which are taken before infusions to manage potential side effects)?

Track your symptoms

Keep a journal to note changes in symptoms like fatigue, pain, and stomach or digestive issues, and track when they get better or worse. Remember to reach out to your provider to discuss any changes.

Even if you're on treatment, monitoring its success is crucial to your journey.

Picture a treatment made with your needs in mind

The best way to manage your Fabry is to stay on treatment. Elfabrio has been shown to be well tolerated and provide long-term results.

Clinical trials have shown Elfabrio results in:

- Low rates of infusion-associated reactions (IARs). See pages 16-17 for more details.
- Reduced need for premedications. See page 21.
- Low rates of treatment-emergent adverse events (TEAEs). See pages 16-18.
- Slowed disease progression (just as well as Fabrazyme® [agalsidase beta]). See page 14.
- Low rates of newly developed ADAs in people who switched from another ERT and in those who were new to ERT.* See pages 17-18.

The data discussed are not intended to establish that Elfabrio is better or is not worse than Fabrazyme on the basis of safety or results. Your experience may vary.

*The impact of ADAs on the effectiveness of Elfabrio is not yet fully understood. The ability to detect these antibodies depends largely on the sensitivity and specificity of the test used.

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Color your life

Elfabrio® (pegunigalsidase alfa-iwxj) is an ERT that was purposefully designed using a process called PEGylation. PEGylation helps Elfabrio stay in your body longer by extending its half-life† (which is how long it takes for the medicine to decrease by half).

Designed differently. Built to last.

Elfabrio is considered long-lasting because:

- The medication stays in your body between doses†
- Enzyme levels increase over time†‡

Measuring infusion-associated reactions (IARs) is a way of assessing how well you tolerate the infusion of a treatment. IARs are any reactions that occur after an infusion. In Elfabrio trials, IARs were tracked within 2 hours after the infusion and within 24 hours.

Adverse events are also known as side effects. **If your doctor determines that a side effect is directly related to your treatment, it is known as a treatment-emergent adverse event (TEAE).**

†Elfabrio has an initial half-life of 78.9 ± 10.3 hours. Clinical studies have not shown that a long half-life results in a medicine working better or more safely. Infusions are every 2 weeks.
‡The average half-life of Elfabrio was measured for 1 year in clinical studies.

Important Safety Information (continued)

What should I know about Elfabrio infusions?

Your healthcare provider may give you other medications prior to your Elfabrio infusions to help manage allergic reactions and infusion-related side effects. They will explain how to recognize the signs and symptoms of these allergic reactions and infusion-related side effects. If these signs and symptoms occur, it's important for you to seek immediate medical care. If the reaction is mild to moderate, your healthcare provider may choose to slow the infusion rate or withhold the dose.

Please see additional Important Safety Information throughout and accompanying Full Prescribing Information, including Boxed Warning.

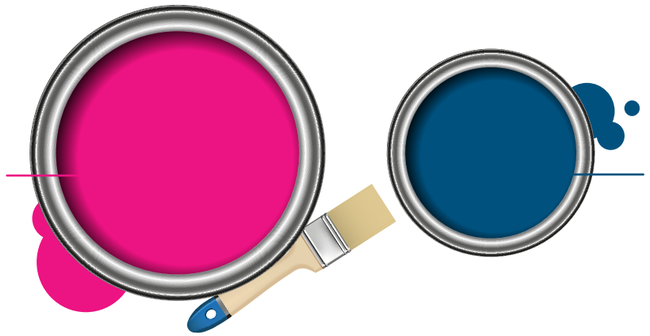
An extensively studied ERT for people living with Fabry

The key trials for FDA approval of Elfabrio were:

The BALANCE Study*:
Studied in people who switched from Fabrazyme

This 2-year key clinical trial included a diverse group of adults who had previously been treated with Fabrazyme and switched to Elfabrio. Their results with Elfabrio were compared to a group of people who stayed on Fabrazyme.

52 people were switched to Elfabrio from Fabrazyme



25 people stayed on Fabrazyme†

The 2-year research showed Elfabrio was proven to work:

Comparable results to Fabrazyme
The rate of change in eGFR was similar in people who switched to Elfabrio from Fabrazyme

Elfabrio has been extensively studied in multiple clinical trials and was FDA approved in 2023.

Maintained kidney function with Elfabrio
Based on this comparison, both ERTs helped maintain kidney function and slowed the progression of disease over the course of the 2-year study‡

*In the Elfabrio Full Prescribing Information, the BALANCE Study is referred to as Trial 2, and the New to ERT Study is referred to as Trial 1.
†People were on Fabrazyme for at least 1 year prior to the study and for an average of approximately 6 years.
‡The FDA noted limitations in the BALANCE Study that make it impossible to draw overall conclusions about Elfabrio in comparison to Fabrazyme. However, the change in eGFR rates was considered comparable between the 2 Fabry treatment options.
FDA, Food and Drug Administration.

Elfabrio: For a fresh start or from the start

ELFABRIO® (pegunigalsidase alfa-iwxj)

The New to ERT Study*:
Studied long term in people who hadn't been on Fabry treatment before or took a break from treatment (≥6 months)

This 1-year study, aimed to determine the appropriate dose, included 18 people who were either new to treatment or hadn't received ERT in the 6 months before the study. An extension study followed the patients for up to 5 more years. The overall trial assessed the safety of Elfabrio and its effect on kidney function for 6 years.

Total duration of the New to ERT Study: 6 years

n=number of people.

Together these studies reflect a diverse group of adults with Fabry:

- √ Both males and females
- √ People who switched from another ERT
- √ People who had never been on an ERT before
- √ People with varying levels of kidney function
- √ People with different levels of ADAs

People new to ERT, or returning to treatment, saw long-term results with Elfabrio:

Stabilized disease progression
Based on 6-year study results

Stable kidney function over time
Based on a kidney function test (eGFR)

Important Safety Information (continued)
What should I know about Elfabrio infusions? (continued)
In clinical trials, 41 patients (29%) experienced an infusion-related side effect. The most common signs and symptoms of an infusion-related reaction with Elfabrio were hypersensitivity, nausea, chills, itchy skin, rash, chest pain, dizziness, vomiting, feelings of weakness, pain, sneezing, shortness of breath, nasal congestion, throat irritation, abdominal pain, skin redness, diarrhea, burning sensation, nerve pain, headache, tingling or numbness, shaking movements, agitation, increased body temperature, flushing, slow heart rate, muscle pain, high blood pressure, and low blood pressure.

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Established safety profile after switching treatments

The BALANCE Study*:
Studied in people who switched from Fabrazyme

Elfabrio was generally well tolerated when studied against Fabrazyme for 2 years. Side effects and IARs were thoroughly assessed.

People who switched to Elfabrio experienced low rates of side effects and IARs compared to those who stayed on Fabrazyme.

On average, people taking Elfabrio had a:

3.6x LOWER
rate of treatment-emergent adverse events*†

7.8x LOWER
rate of infusion-associated reactions*†‡

*Calculating rates, as shown here, helps researchers understand how likely it is that side effects and infusion-associated reactions may happen over time.
†The data discussed are not intended to establish that Elfabrio is better or is not worse than Fabrazyme on the basis of safety or results. These rates are calculated based on the reported data. Your experience may vary.
‡Infusion-associated reactions are not injection site reactions. They are side effects related to treatment that occurred during the infusion or within 2 hours after its completion.

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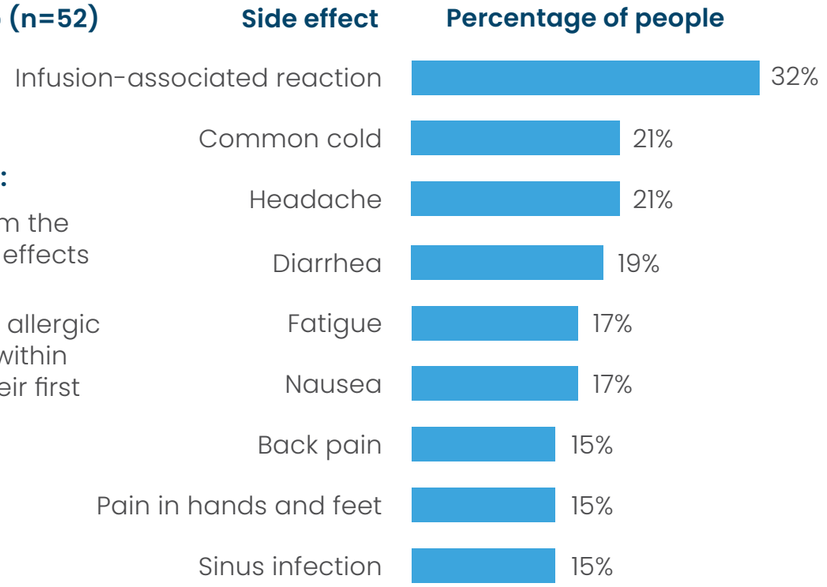
Side effects occurring in over 15% of people taking Elfabrio (n=52)



In people taking Elfabrio:

<4% had to withdraw from the study due to severe side effects

<2% had life-threatening allergic reactions (anaphylaxis) within 40 minutes of starting their first infusion

Please see the Elfabrio Full Prescribing Information for more information regarding rates of side effects in both treatment arms in the BALANCE Study.

91% of people taking Elfabrio who were negative for ADAs at baseline remained negative for ADAs throughout the study.§

§The impact of ADAs on the effectiveness of Elfabrio is not yet fully understood. The ability to detect these antibodies depends largely on the sensitivity and specificity of the test used.

Important Safety Information (continued)
What should I know about Elfabrio infusions? (continued)
Your healthcare provider will do blood and urine tests to check your kidney function during treatment with Elfabrio.

The most common side effects of Elfabrio include infusion-related side effects, common cold, headache, diarrhea, fatigue, nausea, back pain, pain in the limbs, and sinus infection.

Please see additional Important Safety Information throughout and accompanying Full Prescribing Information, including Boxed Warning.

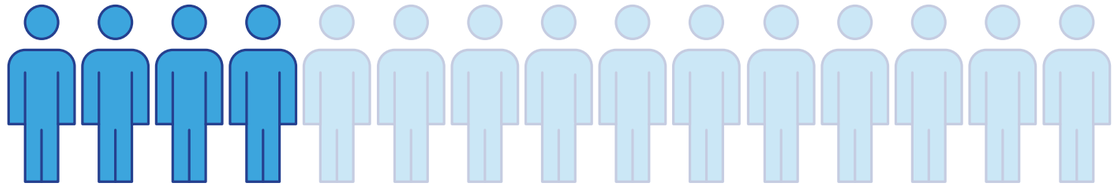
Elfabrio was generally well tolerated in those new to ERT

The New to ERT Study*:
Studied long term in people who hadn't been on Fabry treatment before or took a break from treatment (≥6 months)

In people who had never been on an ERT before or who had stopped treatment for at least 6 months:

- Most side effects were mild or moderate in severity
- 2 people experienced a severe treatment-emergent side effect
  - 1 person experienced a migraine headache that was possibly related to treatment
  - 1 person experienced anaphylaxis (a serious allergic reaction) related to treatment, which led to withdrawal from the study

Only 4 out of 15 people (about 27%) developed ADAs during the 6-year study. Most ADAs resolved on their own within the first year of treatment



Elfabrio: A treatment you can start and stay with

ELFABRIO®
(pegunigalsidase alfa-iwxj)

Any time you switch treatments or start a new treatment, your body has to get used to it at first. Don't stop taking Elfabrio unless directed by your healthcare provider. Maintaining a regular infusion schedule is key to getting consistent results from treatment.

If you have a serious hypersensitivity reaction during the infusion process, the infusion staff or your home health nurse will stop the treatment right away and take appropriate measures.

If you need immediate medical assistance, please dial 911.

If you think you are experiencing a serious side effect with Elfabrio treatment, it is important to call your healthcare provider immediately. In many cases, other side effects are manageable and your provider will have recommendations. Make a note to discuss it at your next visit. Your provider may slow your infusion rate as you adjust to treatment with Elfabrio.

Important Safety Information

What is the most important information I should know about Elfabrio?

Severe allergic reactions (hypersensitivity reactions), including anaphylaxis, may occur during and after Elfabrio treatment. If severe allergic reactions or anaphylaxis occurs during treatment, your healthcare provider will immediately stop the infusion and provide appropriate medical care. If these reactions should occur after treatment, seek immediate medical care.

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Less infusion time may be possible over the course of treatment

Your initial infusions (4 to 6 doses) with Elfabrio will be given every 2 weeks in an infusion center or your doctor's office—this is typical when starting a new treatment.

Sample infusion schedule for ERT-experienced patients

Additional time may be required for premedications depending on the patient.

If your previous ERT infusions lasted over 3 hours, your doctor will likely start your Elfabrio infusions with the same duration. After assessing your tolerance, they may gradually increase the infusion rate to reduce the time required, as shown above.

If you have never been on Fabry treatment before, your initial 4-6 infusions will be at least 4 hours long. This is to help your body get used to treatment.

Sample infusion schedule for patients who are new to ERT

Additional time may be required for premedications depending on the patient.

What to expect with Elfabrio over time

Need for premedications may decrease. When switching to Elfabrio, your healthcare provider may consider continuing premedications from your previous ERT for your initial infusions. Once it's clear that your body is able to tolerate the Elfabrio infusions, your provider may be able to decrease or stop your premedications.*

Infusions in the clinic or at home. With your provider's consent, you may be able to transition to home infusions with an experienced infusion nurse after you have shown you can tolerate Elfabrio and have begun maintenance infusions (insurance permitting).†

*Premedications may include antihistamines, fever reducers, or corticosteroids.
†Please see the accompanying full Terms and Conditions for additional eligibility requirements.

Important Safety Information (continued)

What should I know about Elfabrio infusions?

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Comprehensive patient support

Chiesi TOTAL care℠

Elfabrio provides exceptional one-stop patient support, with individual aid, insurance assistance, and infusion support. Call your dedicated Chiesi Total Care℠ Team, and they will guide you through the process of getting started. A single call is all it takes.*

Individual support
Patient Service Coordinators and Patient Education Liaisons will help you understand your medication and your medical needs.

Insurance assistance
Our Reimbursement Support Specialists will assist with insurance coverage and reimbursement questions.

Infusion support
For eligible Elfabrio patients, Chiesi Total Care offers infusion assistance and copay assistance.

Chiesi Total Care offers 2 copay programs for eligible patients†:

Prescription copay: This covers the medication itself. You may pay as little as $0 for your Elfabrio prescription.

Infusion assistance copay: This covers infusion administration (including home infusion). You may pay as little as $0 for your Elfabrio infusion administration.

To be eligible for these programs:

- You must be enrolled in Chiesi Total Care. (Enrollment and Authorization Form will be mailed to your home)
- You must have commercial insurance and a valid prescription for a US FDA–approved indication for Elfabrio
- You must be a resident of the United States or one of its territories

Please refer to the accompanying full Terms and Conditions for additional eligibility requirements.

Call 1-833-656-1056 or go to chiesitotalcare.com to learn more.

*Chiesi Total Care provides nonfinancial assistance to patients with and without prescription drug coverage.
†Government-funded plans are not eligible for patient support services that provide financial support through the programs. If you are receiving treatment or residing in MA or RI, you are not eligible for home infusion services. To receive home infusion support, you must be referred to home infusion by your prescribing physician.

Important Safety Information

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What should I know about Elfabrio infusions?

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In clinical trials, 41 patients (29%) experienced an infusion-related side effect. The most common signs and symptoms of an infusion-related reaction with Elfabrio were hypersensitivity, nausea, chills, itchy skin, rash, chest pain, dizziness, vomiting, feelings of weakness, pain, sneezing, shortness of breath, nasal congestion, throat irritation, abdominal pain, skin redness, diarrhea, burning sensation, nerve pain, headache, tingling or numbness, shaking movements, agitation, increased body temperature, flushing, slow heart rate, muscle pain, high blood pressure, and low blood pressure.

Your healthcare provider will do blood and urine tests to check your kidney function during treatment with Elfabrio.

The most common side effects of Elfabrio include infusion-related side effects, common cold, headache, diarrhea, fatigue, nausea, back pain, pain in the limbs, and sinus infection.

Please see the accompanying Full Prescribing Information for Elfabrio.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Picture Fabry treatment designed to meet your needs

Stays in your body longer
A long half-life means Elfabrio stays in your body between doses*

Generally well tolerated
Low rates of infusion reactions, adverse events, and anti-drug antibodies†‡

Long-term results
Stable disease progression in a 6-year study§

*Elfabrio has an initial half-life of 78.9 ± 10.3 hours. Clinical studies have not shown that a long half-life results in a medicine working better or more safely. Infusions are every 2 weeks.

†Rates of IARs, TEAEs, and ADAs can be found on pages 16-18.

‡The impact of ADAs on the effectiveness of Elfabrio is not yet fully understood. The ability to detect these antibodies depends largely on the sensitivity and specificity of the test used.

§Trials within the Full Prescribing Information extend up to 2 years. Results from the 6-year New to ERT Study were published in a medical journal.

Talk to your doctor, visit elfabrio.com, or scan the QR code to find out more.

Important Safety Information (continued)

What should I know about Elfabrio infusions? (continued)

In clinical trials, 41 patients (29%) experienced an infusion-related side effect. The most common signs and symptoms of an infusion-related reaction with Elfabrio were hypersensitivity, nausea, chills, itchy skin, rash, chest pain, dizziness, vomiting, feelings of weakness, pain, sneezing, shortness of breath, nasal congestion, throat irritation, abdominal pain, skin redness, diarrhea, burning sensation, nerve pain, headache, tingling or numbness, shaking movements, agitation, increased body temperature, flushing, slow heart rate, muscle pain, high blood pressure, and low blood pressure.

Please see additional Important Safety Information throughout and accompanying Full Prescribing Information, including Boxed Warning.

Chiesi
global rare diseases

PP-RA-00032 V1.0

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(pegunigalsidase alfa-iwxj)