For adults with **Fabry disease**

Picture what long-lasting treatment can do*

Because a lot can happen between doses

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.
†Trials within the Full Prescribing Information extend up to 2 years.

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 complete Important Safety Information on page 23. Also see the accompanying Full Prescribing Information for Elfabrio, including Boxed Warning.

ELFABRIO®
(pegunigalsidase alfa-iwxj)

Life **in full color**

Life with Fabry may not be picture perfect, but understanding your disease and how to manage it can empower you to paint your future in a whole new light.

Picture Elfabrio in your life and what long-lasting* treatment could mean for you and your family. Learn more on the following pages.

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As you go through each section, you will notice underlined words that may be unfamiliar. You can find their definitions in the glossary on pages 20 and 21.

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.

ELFABRIO® (pegunigalsidase alfa-iwxj)

Managing **Fabry can be challenging**

Fabry is a progressive disease, which means it usually **gets worse over time**. Early diagnosis and treatment can increase your chances of managing Fabry symptoms and slowing down disease progression. **Many people with Fabry disease put off treatment** until symptoms become serious, at which time organ damage may have already begun.

While living with Fabry, ongoing issues can make life difficult.

People who have started Fabry treatment might find it challenging. In fact, any of the following issues may impact your motivation to stay on treatment:

How well treatment is working,
including its effects on new symptoms or how often symptoms or Fabry crises occur

Side effects,
including anything from fever and chills to nausea and dizziness, making it difficult to stay on treatment over time

Infusion times
may already be long, and premedications can add additional time to each treatment

What are Fabry crises?

Many people with Fabry disease experience Fabry crises, which are episodes of severe pain, fever, and burning sensations that usually occur in the hands and feet. These crises can last between a few hours to several days.

Living with Fabry today— **and keeping your eye on tomorrow**

It's important to find a treatment you can stick with when you have a progressive disease like Fabry. Working with your doctor can help.

Is your treatment effective...

between doses?

over time?

Monitoring your body's response to Fabry treatment

Has your doctor tested for ADAs?

Testing for anti-drug antibodies (ADAs) is one way doctors can understand how your body is reacting to a medicine.

What are ADAs?

ADAs may develop when your immune system reacts to a drug, causing your body to produce antibodies against ("anti") the drug. ADAs have the potential to affect how well a drug works in your body.

Talk to your doctor about monitoring your ADA status to make sure your treatment is working for you.

Designed with **your needs in mind**

Elfabrio® (pegunigalsidase alfa-iwxj) is an enzyme replacement therapy (ERT) that was purposefully designed using a process called PEGylation (*peg-eh-lay-shun*). This process extends the half-life* so **Elfabrio can work for a long time in your body**.

The Elfabrio half-life was also shown to increase over time as the medication stays in your body.

Elfabrio
half-life reaches

DAY 1	MONTH 6	MONTH 12
~80 HOURS	~96 HOURS	~120 HOURS
78.9 ± 10.3 hours	96.5 ± 31.4 hours	121 ± 22 hours

A long half-life lets your doctors know that the medication in your body is measurable from infusion to infusion. This may help to show that your Elfabrio treatment is still present from dose to dose.

*Clinical studies have not shown that a long half-life results in a medicine working better or more safely.

What is the half-life?

The half-life of a treatment is how long it takes for the amount of the medicine in your body to decrease by half.

Please see complete Important Safety Information on page 23.
Also see the accompanying Full Prescribing Information for Elfabrio, including Boxed Warning.

Picture a **treatment built to last**

What should I know about Elfabrio?

- Long half-life*
- Stays in your body between doses*
- Half-life continues to increase over time*†

†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? (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.

ELFABRIO® (pegunigalsidase alfa-iwxj)

An extensively studied ERT for Fabry

There are only about 11,000 people in the United States living with diagnosed Fabry. Elfabrio was evaluated in 8 international clinical trials that included **142 people**.

The key trials for FDA approval were:

- **The BALANCE Study*** (for people who switched treatments)
- **The New to ERT Study*** (for people who hadn't been treated before or for those not treated at least 6 months before the start of the study)

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

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

See BALANCE Study results on pages 11-13.

See New to ERT Study results on pages 14-15.

*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.
FDA, Food and Drug Administration.

Elfabrio: **Studied against another ERT**

How doctors studied Elfabrio in people like you

In BALANCE, our 2-year key clinical trial, a diverse group of adults who had previously been treated with Fabrazyme® (agalsidase beta) were switched over to Elfabrio. Their results with Elfabrio were compared to those of a control group that stayed on Fabrazyme.†

BALANCE study design: 2-year comparison

†The data discussed are not intended to establish that Elfabrio is better or is not worse than Fabrazyme. Please see the FDA Approval Package available at Drugs@FDA for more information.
‡People were on Fabrazyme for at least 1 year prior to the study and for an average of approximately 6 years.

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.

Please see complete Important Safety Information on page 23. Also see the accompanying Full Prescribing Information for Elfabrio, including Boxed Warning.

ELFABRIO® (pegunigalsidase alfa-iwxj)

Evaluated effectiveness in people who switched from another ERT

Some of the ways that Elfabrio was assessed include:

Kidney function

A primary focus of this study was to assess kidney function for people taking Elfabrio in comparison to those who stayed on Fabrazyme. This was measured by estimated glomerular filtration rate (eGFR) levels, which can help your doctors understand how well your kidneys are working.

Immune response (ADAs)

Another focus of the study was to understand changes in the immune system during Elfabrio treatment. Researchers tested for ADAs at the start of the trial and monitored for changes in ADA tests throughout the study.

*In the Elfabrio Full Prescribing Information, the BALANCE Study is referred to as Trial 2.

Long-term results: 2-year data

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

Maintained kidney function with Elfabrio

The rate of change in eGFR was similar in people who switched to Elfabrio (–2.4) to those who stayed on Fabrazyme (–2.3). Based on this comparison, both ERTs helped maintain kidney function and slow the progression of disease over the course of the 2-year study.†

Low immune response‡

People who switched to Elfabrio experienced a low rate of newly developed ADAs. 31 out of 34 people (91%) taking Elfabrio who were negative at the start of the study remained ADA negative throughout the study.

Clinical significance of total ADAs and their effect on treatment is not completely understood. Talk to your doctor about testing and monitoring for ADAs during treatment.

†The FDA has indicated that there were limitations in the BALANCE Study (for example, differences in patient population), such that it could not conclude whether Elfabrio performed the same as or not worse than Fabrazyme. Nonetheless, the FDA stated that the rate of change in eGFR was comparable between the treatments.

‡The clinical effect of ADAs on the effectiveness of Elfabrio is not fully understood. The detection of antibody formation depends a lot on the test that is conducted. There was no statistical difference for trends in ADAs between the 2 treatment groups from the beginning to Week 104.

ELFABRIO® (pegunigalsidase alfa-iwxj)

Established safety profile
after switching treatments

Elfabrio was well tolerated and people taking it were able to stay on treatment for 2 years. Side effects and infusion-associated reactions were thoroughly examined. Safety results from the key study are listed below.

The most common adverse reactions that occurred in at least 15% of patients† were:

- Infusion-associated reaction
- Common cold
- Headache
- Diarrhea
- Fatigue
- Nausea
- Back pain
- Pain in arms and legs
- Sinus infection

*In the Elfabrio Full Prescribing Information, the BALANCE Study is referred to as Trial 2.
†Please see the Elfabrio Full Prescribing Information for more information regarding rates of adverse reactions in both treatment arms in the BALANCE Study.

Important Safety Information (continued)

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 complete Important Safety Information on page 23.
Also see the accompanying Full Prescribing Information for Elfabrio, including Boxed Warning.

Low rates of side effects and infusion-related reactions‡§

In this study, when researchers compared the safety results for people who switched to Elfabrio to those who stayed on Fabrazyme:

People taking Elfabrio had at least a

3x lower

rate of side effects related to treatment

People taking Elfabrio had at least a

7x lower

rate of infusion-related reactions§

Calculating rates, as shown here, helps researchers understand how likely it is that side effects and infusion-related reactions may happen over time.

Differences in rates of treatment-related side effects and infusion-related reactions were observed in the 2 treatment groups. The ADA-positive group (people who became ADA positive at any time throughout the study) were more likely than people who didn't develop ADAs to experience side effects and/or infusion-related reactions.

	ADA Positive		ADA Negative	
	People taking **Elfabrio** (18 people)	People taking **Fabrazyme** (8 people)	People taking **Elfabrio** (34 people)	People taking **Fabrazyme** (17 people)
Rate of side effects (considered related to treatment)	**87.18**	**295.80**	**20.08**	**83.64**
Rate of infusion-related reactions	**0.9**	**7.5**	**0.3**	**2.2**

‡The data discussed are not intended to establish that Elfabrio is better or is not worse than Fabrazyme on the basis of safety or efficacy. These rates are calculated based on the reported data. Your experience may vary.
§Infusion-related 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.

ELFABRIO® (pegunigalsidase alfa-iwxj)

Studied over time in people who had never been on Fabry treatment before

How doctors studied Elfabrio in people like you

The other key trial from the Full Prescribing Information evaluated 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 years. The trial assessed the safety of Elfabrio and its effect on kidney tests.

Long-term results

Helped maintain kidney function and slow disease progression, based on results from a 5-year study

A kidney function test (known as eGFR) showed that both men and women maintained stability over time

*In the Elfabrio Full Prescribing Information, the New to ERT Study is referred to as Trial 1.

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.

Elfabrio was **well tolerated**

Assessing treatment safety

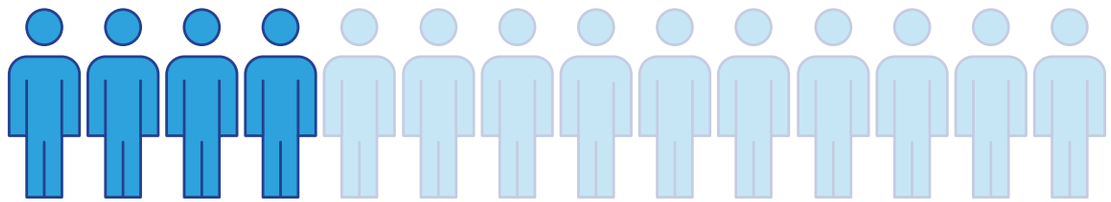
In people who had never been on an ERT before or who had stopped treatment for at least 6 months:

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

Assessing immune system response

In people who were ADA negative at the start of Elfabrio treatment and had ADA-testing results available:

Only 4 out of 14 people (28%) became ADA positive during the 1-year treatment period.



Elfabrio: A treatment you can start and stay with

Please see complete Important Safety Information on page 23. Also see the accompanying Full Prescribing Information for Elfabrio, including Boxed Warning.

ELFABRIO® (pegunigalsidase alfa-iwxj)

Picture this: Less infusion time 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. Every person is different, so in addition to the Elfabrio infusion time, more time may be needed for premedications.

Sample infusion schedule for ERT-experienced patients

If you were previously treated with an ERT and your infusions lasted longer than 3 hours, your doctor will likely use that same infusion time for your initial Elfabrio infusions. Once it's clear whether your body can tolerate the Elfabrio infusions, your doctor may gradually speed up the rate of infusion to decrease the time, as shown above.

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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What to expect with Elfabrio over time

Decreasing infusion times

After the first 4 to 6 infusions and once your doctor confirms your body is handling Elfabrio well, the infusion time may be decreased. Depending on your body weight and other factors, your maintenance infusions may be as short as 1.5 hours.

Need for premedications may decrease

When switching to Elfabrio, your doctor 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 doctor may be able to decrease or stop your premedications.*

Infusions in the clinic or at home

With your doctor's consent, you may be able to transition to home infusions with a certified infusion nurse after you have shown you can tolerate Elfabrio and begun maintenance infusions (insurance permitting).† If you receive infusions at home, Chiesi Total Care may be able to assist, if eligible, with delivery of medication and infusion supplies.

*Premedications may include antihistamines, fever reducers, or corticosteroids.
†If you are receiving treatment or residing in MA or RI, you are not eligible for infusion assistance. Please see the accompanying full Terms and Conditions for additional eligibility requirements.

ELFABRIO® (pegunigalsidase alfa-iwxj)

Comprehensive patient support

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.*

Chiesi TOTAL care℠

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 provides nonfinancial assistance to patients with and without prescription drug coverage.

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

Help when you need it

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 Food and Drug Administration (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.

†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.

Patient Welcome Kit

Once you're prescribed Elfabrio, you will receive a Patient Welcome Kit. This kit includes information and resources to help you understand your treatment.

Please see complete Important Safety Information on page 23. Also see the accompanying Full Prescribing Information for Elfabrio, including Boxed Warning.

ELFABRIO® (pegunigalsidase alfa-iwxj)

Fabry glossary

The following terms are underlined throughout this brochure. Use these definitions to gain a better understanding of your Fabry treatment.

anaphylaxis (*a-nuh-fuh-lak-sis*)**:** This is a serious and potentially fatal allergic reaction with a variety of signs and symptoms that often require immediate medical attention on-site and in the emergency room.

anti-drug antibodies, or ADAs: ADAs may develop when your immune system reacts to a drug, causing your body to produce antibodies against ("anti") the drug. ADAs have the potential to affect how well a drug works in your body.

enzyme replacement therapy, or ERT: ERT is a medical treatment that replaces an enzyme in your body that is working improperly or missing.

estimated glomerular (*gluh-mare-yuh-ler*) **filtration rate, or eGFR:** eGFR is a test that measures your level of kidney function. It helps determine your stage of kidney disease.

Fabry crises (*cry-sees*)**:** Many people with Fabry disease experience Fabry crises, which are episodes of severe pain, fever, and burning sensations that usually occur in the hands and feet. These crises can last between a few hours to several days.

half-life: The half-life of a treatment is how long it takes for the amount of the medicine in your body to decrease by half. A long half-life lets your doctors know that the medication in your body is measurable from infusion to infusion.

PEGylation (*peg-eh-lay-shun*) **or a PEGylated medicine:** This means that a chemical compound called PEG, or polyethylene glycol, has been attached to the drug. That process is called PEGylation, and it can give treatments a long half-life.

premedications/pretreatments: These are medications such as antihistamines, fever reducers, and/or corticosteroids that your doctor may have you take before your infusion starts. They help to manage the side effects or reactions you may experience from your medication or the infusion.

Managing expectations and side effects

IF YOU NEED IMMEDIATE MEDICAL ASSISTANCE, PLEASE DIAL 911.

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

Any time you switch treatments or start a new treatment, your body has to get used to it at first. Don't get discouraged or stop taking Elfabrio unless directed by your doctor. Maintaining a consistent 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.

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.

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.

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**

Long half-life*

Well tolerated

Long-term results†

*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.
†Trials within the Full Prescribing Information extend up to 2 years.

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

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Chiesi
global rare diseases

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ELFABRIO®
(pegunigalsidase alfa-iwxj)