



**Some things need a lot of time. A pill for Fabry disease isn't one of them.**

**Galafold® (migalastat) is the first and only oral therapy for adults with confirmed Fabry disease and an amenable *GLA* variant.**



## **Indication and Select Important Safety Information**

### **What is Galafold?**

Galafold® (migalastat) is a prescription medicine used to treat adults with Fabry disease who have a certain genetic change (variant) in the galactosidase alpha gene (*GLA*) that is responsive (amenable) to Galafold. It is not known if Galafold is safe and effective in children.

**Before taking Galafold, tell your healthcare provider about all of your medical conditions, including if you:**

- have kidney problems.
- are pregnant or plan to become pregnant. It is not known if Galafold will harm your unborn baby.
- are breastfeeding or plan to breastfeed. Galafold may pass into breast milk. Talk to your healthcare provider about the best way to feed your baby if you take Galafold.

**Please see full Important Safety Information on the last page and [click here](#) for Full Prescribing Information, including Patient Information and Instructions for Use, also available at [Galafold.com](http://Galafold.com).**

# Galafold<sup>®</sup> (migalastat) uses the enzyme you already have. It isn't enzyme replacement.



Galafold is the every-other-day oral therapy for adults with confirmed Fabry disease and an amenable *GLA* variant. It works by helping your alpha-galactosidase A do its job.

## What does it mean to use the enzyme you already have?



fatty substances

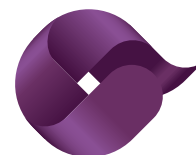
In **Fabry disease**, fatty substances, also referred to as substrates, build up in a cell's lysosome (the cell's recycling center) because they can't be broken down properly. This is because a mutation or change in the galactosidase alpha (*GLA*) gene leads to defective or absent alpha-galactosidase A (alpha-Gal A), the enzyme responsible for breaking down these substances.

### There are many mutations that can cause Fabry disease.

We refer to these as *GLA* variants. Some people with Fabry disease have variants that generate deficient, misfolded alpha-Gal A. This enzyme may just need some help from a chaperone like Galafold to work properly.



misfolded alpha-Gal A



properly folded  
alpha-Gal A

## Important Safety Information (continued)

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take medicines or supplements containing caffeine as these medicines or supplements may affect how Galafold works.

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## Know your variant.

Galafold can only work for amenable *GLA* variants. Talk to your healthcare provider to see if Galafold may be right for you.



“I got connected with a wonderful genetic counselor. She sent me paperwork to get me and my son genetically tested.”

– Rebecca, on her and her son’s variant testing

“I found out about a possible treatment that was in development. I was told there would be a trial starting soon, and they needed to run some tests to see if I fit the criteria for their study...It turned out that my variant was amenable for the treatment. Later, that treatment was approved as Galafold and I’ve been on it ever since.”

– Alex, on his variant testing



## Important Safety Information (continued)

### How should I take Galafold?

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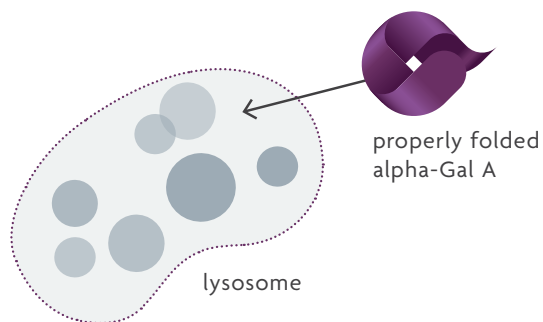
# The first and only oral therapy for Fabry disease

"I was so relieved to have a treatment that I could take orally for Fabry."

– Rebecca, on finding out about Galafold



In order to break down fatty substances, alpha-Gal A needs to travel into the lysosome. But usually only properly folded enzymes make it into this part of the cell. Misfolded enzymes, like some of those seen in Fabry disease, cannot enter the lysosome and are broken down instead. For adults with an amenable gene variant, that's where Galafold® (migalastat) may help.



Even if you've had a test in the past that determined you have little or no enzyme activity, your variant may still be amenable to Galafold. It may just mean your enzyme can't get to the lysosome to do its job.

## Important Safety Information (continued)

### What are the possible side effects of Galafold?

The most common side effects of Galafold include headache, stuffy or runny nose and sore throat, urinary tract infection, nausea, and fever.

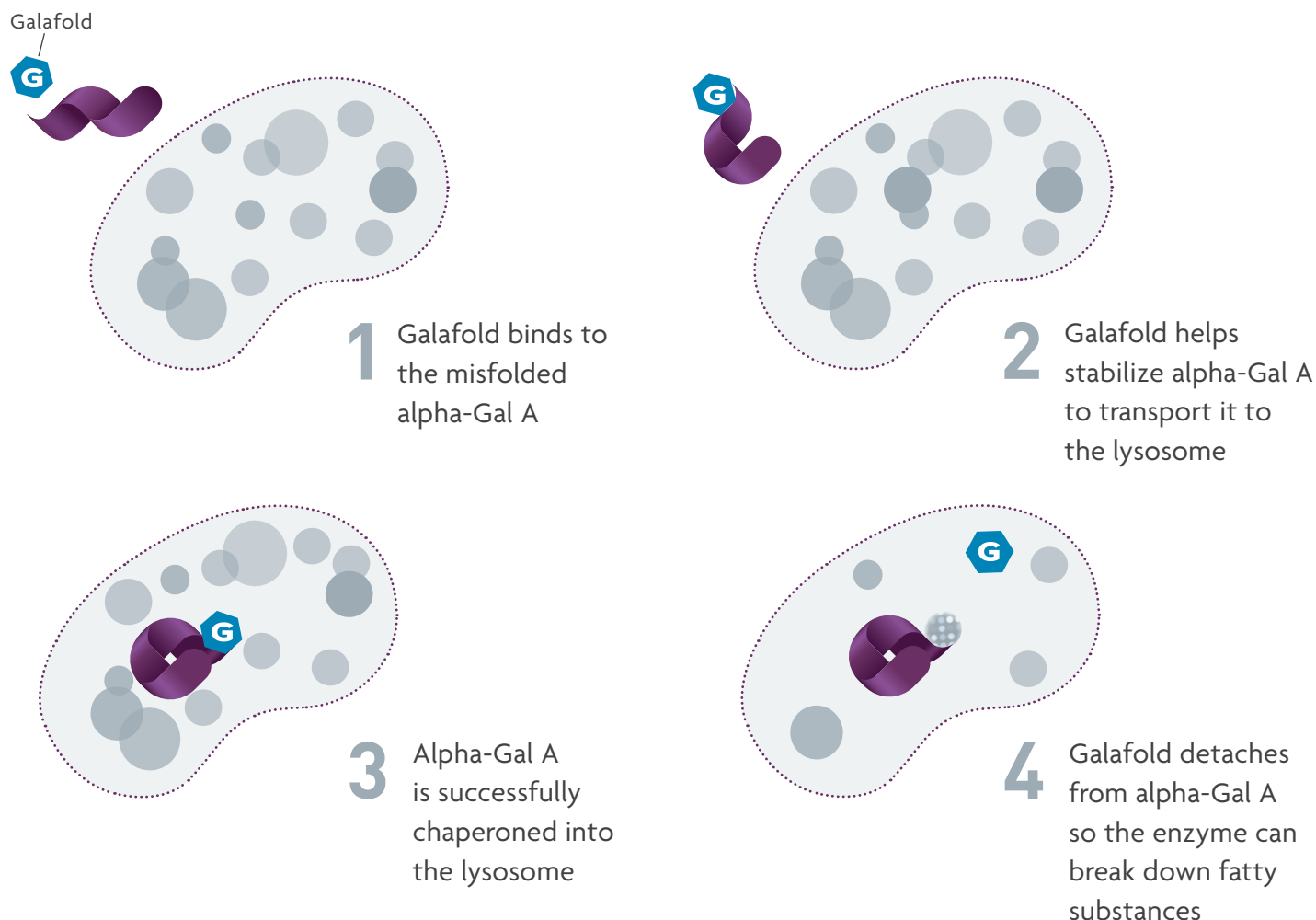
These are not all the possible side effects of Galafold. Call your healthcare provider for medical advice about side effects.

You may report side effects to FDA at [1-800-FDA-1088](tel:1-800-FDA-1088). You may also report side effects to Amicus Therapeutics at [1-877-4AMICUS](tel:1-877-4AMICUS).

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## Galafold is a pharmacological chaperone.

As a chaperone, Galafold works by binding to the misfolded alpha-Gal A in individuals with an amenable **GLA** variant. This stabilizes the enzyme so it can get into the lysosome. Once inside, Galafold detaches from alpha-Gal A, allowing it to get to work breaking down fatty substances.



### Important Safety Information (continued)

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- are breastfeeding or plan to breastfeed. Galafold may pass into breast milk. Talk to your healthcare provider about the best way to feed your baby if you take Galafold.

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# Every other day is Galafold<sup>®</sup> (migalastat) day.

Why every other day? To give your alpha-Gal A enough time to break down those fatty substances. For help keeping track, look to your Galafold pack.



“When I start a new package of Galafold, I like to write the day of the week above the capsule. I keep the package by my easy chair and it has become a habit to check it as the last thing I do before bed.”

– Joyce, on her Galafold tracking

## Important Safety Information (continued)

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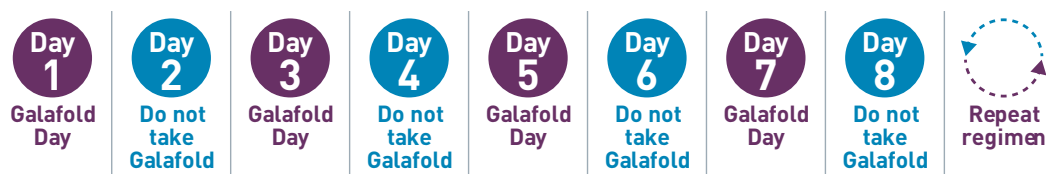
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## How to Take Galafold.

Galafold is taken every other day at the same time of day and building Galafold into your routine can make it easier to remember.

## Record your pill time so you take Galafold on time.

When life gets hectic, it can be hard to remember pill time—especially if Galafold is a new step in your routine. That's why each Galafold pack is made to help you keep track.



“I learned how to take Galafold so that it worked for me. I liked that it was a pill. I liked being able to take it at home without having to schedule doctor’s visits or appointments.”

– Alex, on his Galafold routine



## Important Safety Information (continued)

### How should I take Galafold?

**Do not** eat food, or take or drink any product that contains caffeine at least 2 hours before **and** 2 hours after taking Galafold to give a minimum 4 hour fast.

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# When to take Galafold<sup>®</sup> (migalastat)? When the time is good for you.

Taking Galafold takes about a minute. When that minute happens is up to you, based on your routine and your eating schedule.

## Pick a time that's convenient.

Because Galafold needs to be taken at the same time of day on an empty stomach, pick a time that works best for you and your eating schedule. The time doesn't matter, as long as you are consistent.



**If you miss a dose of Galafold, take the missed dose of Galafold** within 12 hours of your normal schedule. If more than 12 hours have passed, do not make up the missed dose. You should resume taking Galafold at your next scheduled day and time following your original every-other-day dosing schedule.

## Important Safety Information (continued)

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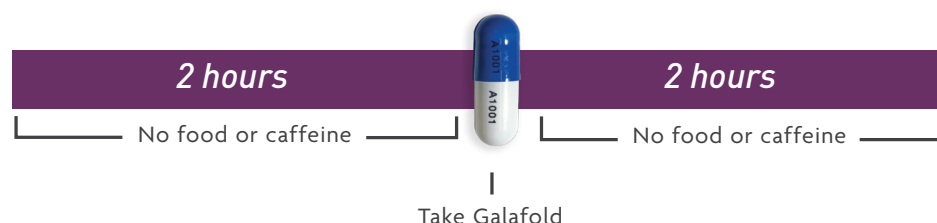
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## Galafold must be taken on an empty stomach.

**Do not** eat food, or take or drink any product that contains caffeine at least 2 hours before **and** 2 hours after taking Galafold to give a minimum 4 hour fast.

You can drink the following during this time when you cannot eat:

- **Water**  
Plain, flavored, or sweetened
- **Fruit juices without pulp**
- **Caffeine-free carbonated beverages**



“I found it very simple to fast once I started. For me, I stop eating and drinking caffeine 2 hours before I go to bed. I don’t even think about it after the medication because I’m asleep.”

– Rebecca, on her Galafold routine



### Important Safety Information (continued)

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# For adults prescribed Galafold<sup>®</sup> (migalastat), AMICUS ASSIST<sup>®</sup> is a call away.

AMICUS ASSIST is a free service to help provide you with product assistance and support.\*

\*Individuals must be prescribed Galafold for an approved use to be eligible for support from AMICUS ASSIST.



Rebecca, an actual Galafold patient

## Get dedicated support.

Once your healthcare provider has prescribed Galafold,\* AMICUS ASSIST will provide you with a dedicated **Case Manager** and **Patient Education Liaison (PEL)** who will be your points of contact for accessing the support services.

### What is a Patient Education Liaison (PEL)?

Your dedicated PEL will offer education and support by:



Answering questions about Fabry disease and your Amicus medication



Providing tips to help you establish a treatment routine



Helping you have more productive conversations with your care team

Please remember, while your PEL is available to provide support throughout your treatment, PELs do not provide medical advice. Your healthcare provider is your go-to resource for any questions related to your care.

### What is a Case Manager?

Your Case Manager will help you navigate treatment access and financial resources by:



Verifying and explaining your insurance coverage



Helping coordinate your prescription deliveries



Identifying possible sources of financial assistance

### How can both help me?

With the combined knowledge and expertise of a PEL and a Case Manager, we can work together to ensure that your care team has all the information they need to support your treatment with an Amicus medication.

**Questions?**  
**Connect with an AMICUS ASSIST team member.**  
**Call 1-833-AMICUS-A (1-833-264-2872)**  
Monday–Friday | 8AM–8PM ET



**FIRST  
AND  
ONLY**

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amenable *GLA* variant

## Important Safety Information

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