

# THIS IS YOUR GUIDE

## How to take Galafold (migalastat)

### IMPORTANT SAFETY INFORMATION

#### **What is Galafold?**

Galafold 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.

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

**Please see additional Important Safety Information throughout and full Important Safety Information on back cover. See accompanying full Prescribing Information, including Patient Information.**

# INSTRUCTIONS FOR USE

## Important

Read this Instructions for Use before you start taking Galafold (migalastat) and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.



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# KEY INFO

Always read the full Instructions for Use.

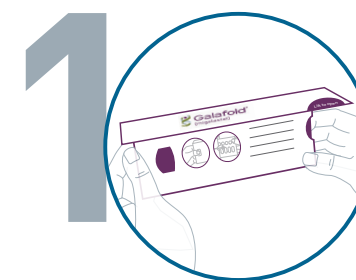
- ▶ Take 1 Galafold (migalastat) capsule every **other** day at the same time of day.
- ▶ **Do not** take Galafold two days in a row.



- ▶ Take Galafold on an empty stomach.
- ▶ **Do not** eat at least 2 hours before **and** 2 hours after taking Galafold. You may drink clear liquids during this 4-hour time when you cannot eat.
- ▶ Swallow the Galafold capsule whole. Do not cut, crush, or chew the Galafold capsule.

Replace the blister card back in the carton after use.

## Opening the Carton



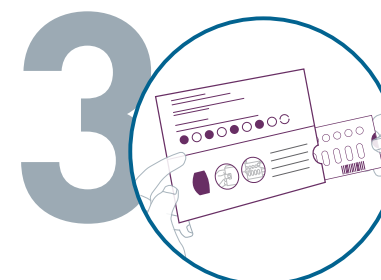
### LIFT

Lift the cover of your Galafold (migalastat) capsule carton.



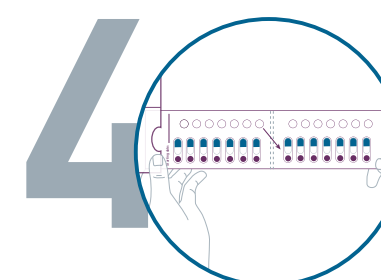
### PRESS

Press and hold down the purple tab on the left side of the carton.



### PULL

Hold the purple “pull” tab on the right side of the carton and pull out the blister card.



### UNFOLD

Unfold the blister card.

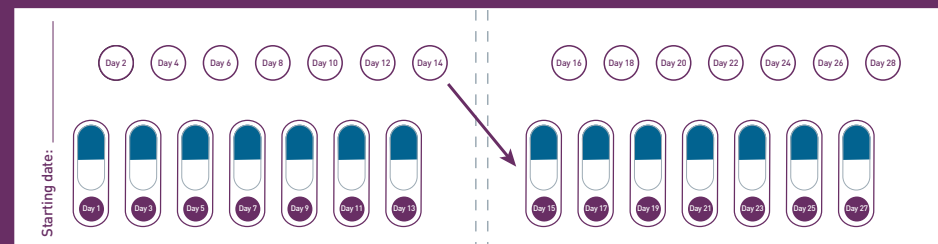
Tip: Press hard to allow the blister card to come out.

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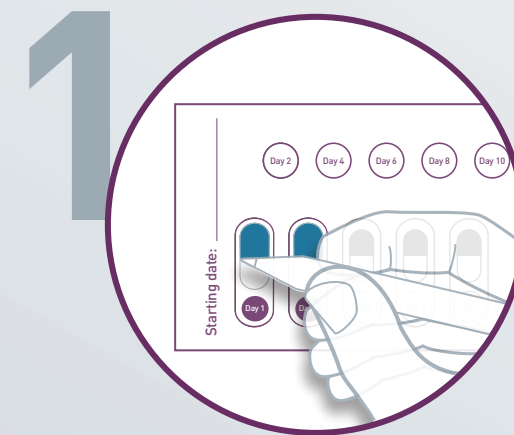


# TAKING GALAFOLD (migalastat)

Each Galafold blister card contains 14 Galafold capsules (enough for 28 days of treatment with Galafold) and 14 white cardboard circles. The white cardboard circles are to remind you to take Galafold every **other** day.



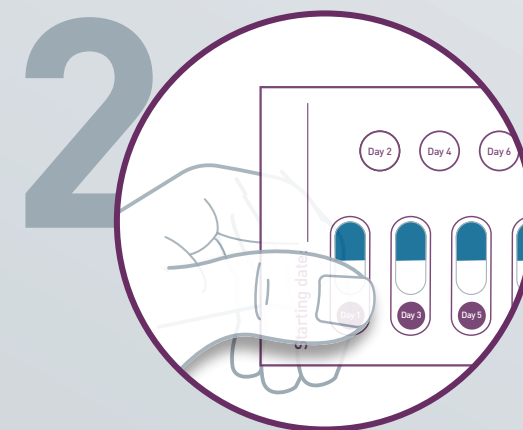
Tip: Remember that you should only take 1 Galafold capsule every other day at the same time of day. Do not take Galafold 2 days in a row.



## RECORD

On your first day of taking a Galafold capsule from the new blister card, write the date on the blister card (Starting date).

Tip: It is important to take Galafold on an empty stomach. Do not eat at least 2 hours before and 2 hours after taking Galafold.



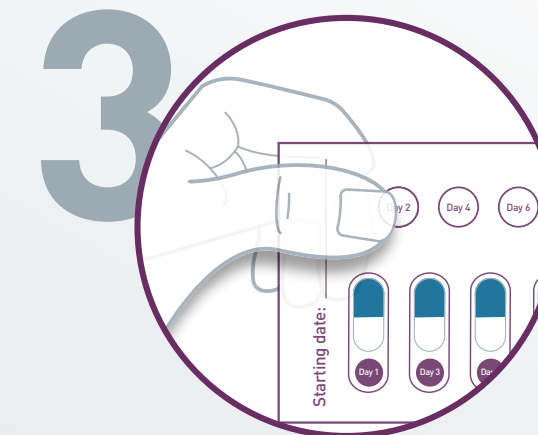
## REMOVE CAPSULE

Remove the Galafold capsule on the bottom row and furthest to the left, that is labeled Day 1, by pressing the capsule through the bottom of the blister card.

Tip: To avoid damaging the capsule, press the bottom of the capsule at an angle. Do not press the center of the capsule, as it may crush the pill. The pill should only be taken whole.

## Important Safety Information

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



## REMOVE CIRCLE

On the next day, remove the white cardboard circle on the top row and furthest to the left, that is labeled Day 2, by pressing down on the circle. Removing this circle will help you remember which day you do not take the medicine. Take 1 Galafold capsule every **other** day.

After Day 2, continue to take 1 capsule or remove 1 white cardboard circle each day in order on the blister card.

Change (alternate) each day between taking 1 Galafold capsule on odd-numbered days (such as Day 1, Day 3, Day 5, and through Day 27) and removing 1 white cardboard circle on even-numbered days (such as Day 2, Day 4, Day 6, and through Day 28).

Replace the blister card back in the carton after each use.

This Instructions for Use has been approved by U.S. Food and Drug Administration.

Manufactured for:  
Amicus Therapeutics U.S., Inc.  
1 Cedar Brook Drive  
Cranbury, NJ 08512  
Galafold is a registered trademark of Amicus Therapeutics, Inc.  
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Please see additional Important Safety Information throughout and full Important Safety Information on back cover. See accompanying full Prescribing Information, including Patient Information.



# DON'T FORGET

Take Galafold (migalastat) on an empty stomach.

► **Do not** eat at least 2 hours before **and** 2 hours after taking Galafold.



Tip: Eating during this 4-hour time period can decrease and delay absorption of Galafold.

## How to Store

► Store Galafold at room temperature between 68°F to 77°F (20°C to 25°C).

► Keep Galafold capsules in the blister card they come in.

**Keep Galafold and all medicines out of the reach of children.**

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## IMPORTANT SAFETY INFORMATION

### What is Galafold (migalastat)?

Galafold 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.

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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

The most common side effects of Galafold were 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 doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Amicus Therapeutics at 1-877-4AMICUS.

**Please see accompanying full Prescribing Information, including Patient Information.**

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