

# How to take Galafold® (migalastat)

#### Indication and Select 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.

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.



#### **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.



## Instructions for Use

#### **Important**

Read the **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.



Your Galafold packaging may look different.

#### **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.

## It's important to remember.

Take 1 Galafold® (migalastat) capsule every other day at the same time of day.

**Do not** take Galafold 2 days in a row.



#### Take Galafold 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 may drink water (plain, flavored, or sweetened), fruit juices without pulp, and caffeine-free carbonated beverages during this time when you cannot eat.
- Swallow the Galafold capsule whole. Do not cut, crush, or chew the Galafold capsule.

"I put my Galafold package right next to my toothbrush.

I see it at night as I am about to go to bed, as I am brushing
my teeth."—Alex, an actual Galafold patient

#### **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.

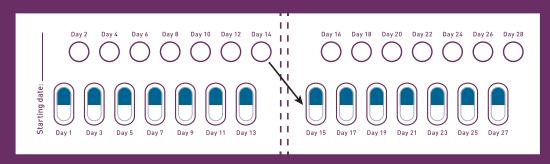
You may report side effects to FDA at <u>1-800-FDA-1088</u>. You may also report side effects to Amicus Therapeutics at <u>1-877-4AMICUS</u>.



# Your pill pack can be used as a tracker.

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.

The arrow directs you to begin the next 2 weeks of treatment.



#### How to store Galafold

- ▶ 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.

#### **Important Safety Information (continued)**

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.

# How to remove and take Galafold® (migalastat) capsules.

Always read the full Instructions for Use.



#### LIFT

Remove the adhesive seal holding the cover. Lift the cover of your Galafold carton.



#### **PRESS**

Press and hold down the purple tab with your thumb at the **left** side of the carton, and continue to step 3.

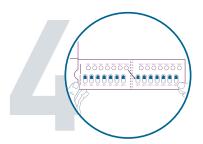


#### **PULL**

GRASP <u>the tab</u> on the **right** side of the blister card where it says "PULL OUT HERE" and pull out the folded blister card.

#### **Important Safety Information (continued)**

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#### **UNFOLD**

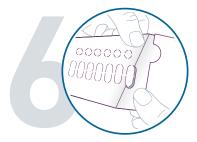
Unfold the blister card.



#### **RECORD**

On your first day of taking Galafold from a new blister card, record the date on the blister card next to "Starting date:"

Tip: It is important to take Galafold 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.



#### **TURN OVER**

Locate the Galafold capsule to remove for the dosing day. <u>TURN</u> the blister card <u>OVER</u> to show the <u>back of the card</u>. BEND the card as shown.

Note: <u>Bending</u> the blister card <u>helps raise</u> the oval perforated cardboard.



#### **REMOVE CARDBOARD**

REMOVE the oval perforated cardboard.

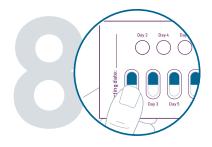
Note: After removing the oval cardboard, the white backing of the foil may be present, which is ok.

#### **Important Safety Information (continued)**

#### How should I take Galafold?

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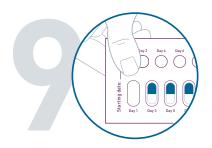




#### **PUSH CAPSULE**

TURN the blister card OVER to show the front of the card. PUSH the Galafold capsule out.

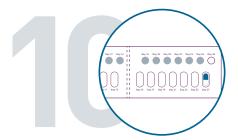
Tip: To avoid damaging the pill, press the bottom of the pill at an angle. Do not press the center of the capsule, as it may crush the pill. The pill should only be taken whole.



#### **NEXT DAY**

On the next day, move to the perforated white cardboard circle on the <u>top row</u>. Press down on the white cardboard circle to remove it.

Note: Removing this white cardboard circle will help you remember which day you do not take Galafold. Take 1 Galafold capsule every **other** day. Fold the blister card, and slide it back into the carton after each use.



#### REPEAT CYCLE

Change (alternate) each day between taking the Galafold capsule and removing the perforated white cardboard circle until you reach Day 28. Start a new blister card when you are finished with Day 28.

#### **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 <u>1-800-FDA-1088</u>. You may also report side effects to Amicus Therapeutics at <u>1-877-4AMICUS</u>.

# **Treatment tips**



Take Galafold® (migalastat) 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 beverages during this time when you cannot eat.
  - Water

     Plain, flavored, or sweetened

     Fruit juices without pulp



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Please <u>click here</u> for Full Prescribing Information, including Patient Information and Instructions for Use, also available at Galafold.com.

