



GalafoldTM
(migalastat) 123 mg
capsule

How to take Galafold

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 an enzyme called alpha-galactosidase A (*GLA*) that is responsive (amenable) to Galafold.

It is not known if Galafold is safe and effective in children.

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



Galafold™

(migalastat) 123 mg capsule

Instructions for Use for Galafold

Important

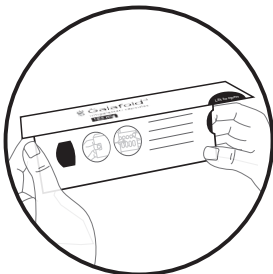
Read this Instructions for Use before you start taking Galafold and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Important information:

- Take 1 Galafold 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.

Opening the Galafold capsule carton:

Figure A



Step 1. Lift the cover of your Galafold capsule carton (See Figure A).

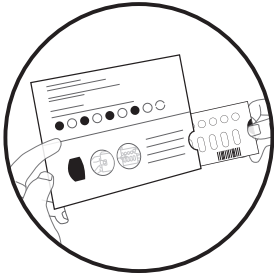
Figure B



Step 2. Press and hold down the purple tab on the left side of the carton (See Figure B).

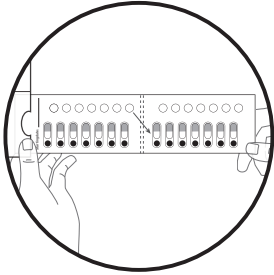
Please see Important Safety Information throughout and accompanying Full Prescribing Information, including Patient Information.

Figure C



Step 3. Hold the purple “pull” tab on the right side of the carton and pull out the blister card (See Figure C).

Figure D



Step 4. Unfold the blister card (See Figure D).

Taking Galafold capsules:

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 (See Figure E).

Figure E

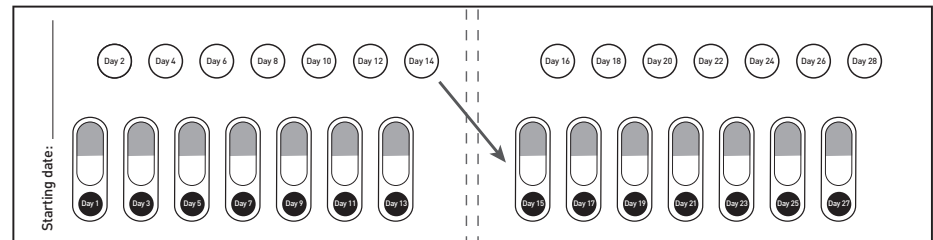
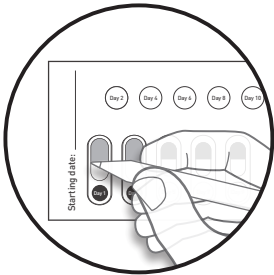
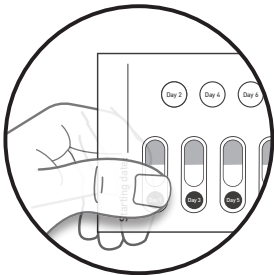


Figure F



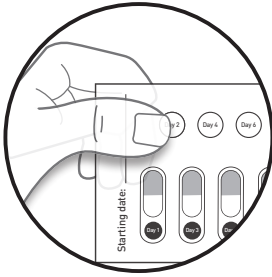
Step 1. On your first day of taking a Galafold capsule from a new blister card, write the date on the blister card (Starting date) (See Figure F).

Figure G



Step 2. Remove the Galafold capsule on the bottom row and furthest to the left, that is labelled Day 1, by pressing the capsule through the bottom of the blister card (See Figure G).

Figure H



Step 3. On the next day, remove the white cardboard circle on the top row and furthest to the left that is labelled Day 2 by pressing down on the circle (See Figure H). 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 the 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.

How should I 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.

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

Manufactured for:

Amicus Therapeutics U.S., Inc.

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Galafold™ is a trademark of Amicus Therapeutics, Inc.

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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 healthcare provider 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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