

## Package leaflet: Information for the patient

### Galafold 123 mg hard capsules

migalastat

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

1. What Galafold is and what it is used for
2. What you need to know before you take Galafold
3. How to take Galafold
4. Possible side effects
5. How to store Galafold
6. Contents of the pack and other information

#### 1. What Galafold is and what it is used for

Galafold contains the active substance migalastat.

This medicine is used for the long-term treatment of Fabry disease in adults and adolescents aged 12 years and older who have certain genetic mutations (changes).

Fabry disease is caused by the lack of or a faulty enzyme called alpha-galactosidase A ( $\alpha$ -Gal A). Depending upon the kind of mutation (change) in the gene that produces  $\alpha$ -Gal A, the enzyme does not work properly or is completely absent. This enzyme defect leads to abnormal deposits of a fatty substance known as globotriaosylceramide (GL-3) in kidneys, heart, and other organs, leading to the symptoms of Fabry disease.

This medicine works by stabilising the enzyme that your body produces naturally, so that it can work better to reduce the amount of GL-3 that has accumulated in your cells and tissues.

#### 2. What you need to know before you take Galafold

##### Do not take Galafold if you:

- are allergic to migalastat or any of the other ingredients of this medicine (listed in section 6).

##### Warnings and precautions

123 mg migalastat capsules are not for children ( $\geq 12$  years) weighing less than 45 kg.

Talk to your doctor before taking Galafold if you are currently taking enzyme replacement therapy. You should not take Galafold if you are also receiving enzyme replacement therapy.

Your doctor will monitor your condition and whether your medicine is working every 6 months while you are taking Galafold. If your condition worsens, your doctor may evaluate you further or may discontinue your treatment with Galafold.

Talk to your doctor before taking Galafold if you have severely reduced kidney function as Galafold is not recommended for use in patients with severe renal insufficiency (GFR less than 30 mL/min/1.73m<sup>2</sup>).

## **Children**

### *Children <12 years*

This medicine has not been studied in children under the age of 12 years; therefore, the safety and efficacy in this age group has not been established.

## **Other medicines and Galafold**

Tell your doctor, pharmacist or nurse if you are taking, have recently taken, or might take any other medicines. This includes medicines obtained without a prescription, including supplements and herbal medicines.

Especially tell your doctor if you take caffeine containing medicines or supplements as these medicines may affect how Galafold works if taken during fasting period.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist each time you get a new medicine.

## **Pregnancy, breast-feeding, and fertility**

### *Pregnancy*

There is very limited experience with the use of this medicine in pregnant women. Galafold is not recommended during pregnancy. If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking this medicine.

Women who could become pregnant should use effective birth control while taking Galafold.

### *Breast-feeding*

Do not take this medicine if you are breast-feeding, until you have spoken with your doctor, pharmacist, or nurse. It is not yet known whether this medicine passes into breast milk. Your doctor will decide whether you need to stop breast-feeding or temporarily stop your medicine, considering the benefit of breast-feeding to the baby and the benefit of Galafold to the mother.

### *Fertility in men*

It is not yet known if this medicine affects fertility in men. The effects of Galafold on fertility in humans have not been studied.

### *Fertility in women*

It is not yet known if this medicine affects fertility in women.

If you are planning to have a baby, ask your doctor, pharmacist, or nurse for advice.

## **Driving and using machines**

It is unlikely that this medicine will affect your ability to drive and use machines.

## **3. How to take Galafold**

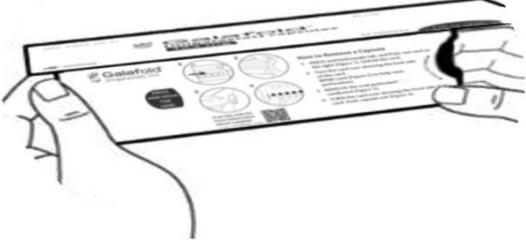
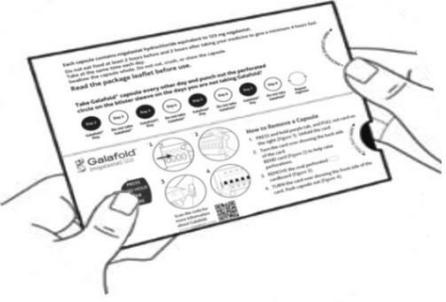
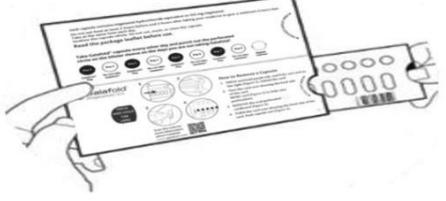
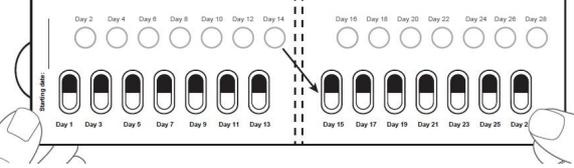
Always take this medicine exactly as your doctor, pharmacist, or nurse has told you. Check with your doctor, pharmacist, or nurse if you are not sure.

Take one capsule every other day at the same time of the day. Do not take Galafold on two consecutive days.

Do not consume food or caffeine at least 2 hours before and 2 hours after taking your medicine. This minimum 4 hours fast around taking your medicine is needed to allow your medicine to be fully absorbed.

Water (plain, flavored, sweetened), fruit juices without pulp, and caffeine-free carbonated beverages can be consumed during the 4-hour fasting period.

Swallow the capsule whole. Do not cut, crush, or chew the capsule.

<p>Figure A</p> 	<p>Step 1: Remove the adhesive seal holding the cover. Lift the cover of your Galafold carton (see Figure A).</p>
<p>Figure B – Opened carton</p> 	<p>Step 2: Press and <u>continue holding down the purple tab with your thumb</u> at the <b>left</b> side of the carton (see Figure B), and continue to Step 3.</p>
<p>Figure C</p> 	<p>Step 3: Now GRASP <u>the tab</u> on the <b>right side</b> where it says “PULL OUT HERE” and pull out the folded blister card (see Figure C).</p>
<p>Figure D – Front of the blister card</p> 	<p>Step 4: Unfold the blister card (see Figure D).</p>

**Taking Galafold Capsule:**

One Galafold blister card = 14 hard capsules = 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 the patient to begin the next 2 weeks of treatment.

Figure E – Front of the blister card

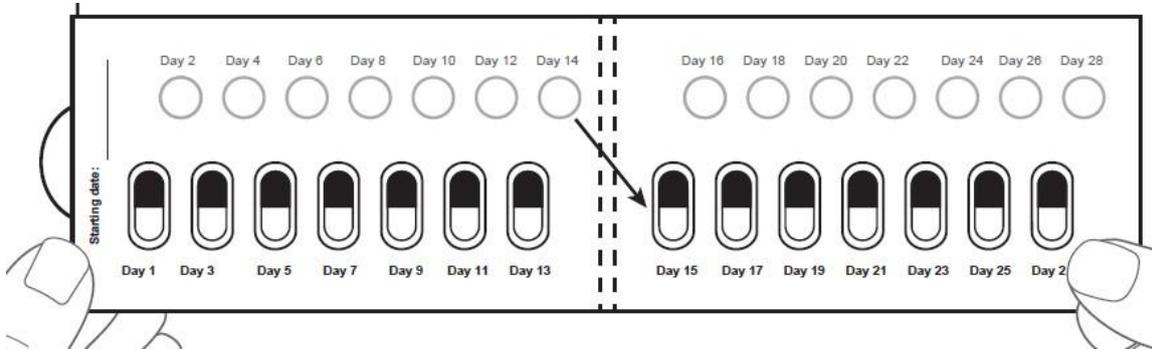
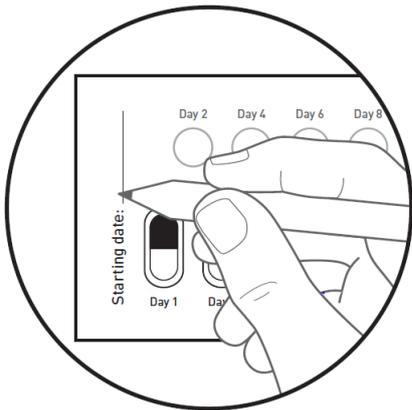
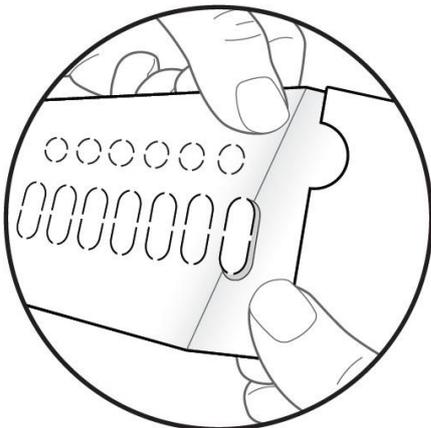


Figure F – Front of the blister card



Step 5: On your first day of taking this medicine from a new blister card, record the date on the blister card (see Figure F).

Figure G – Back of the blister card

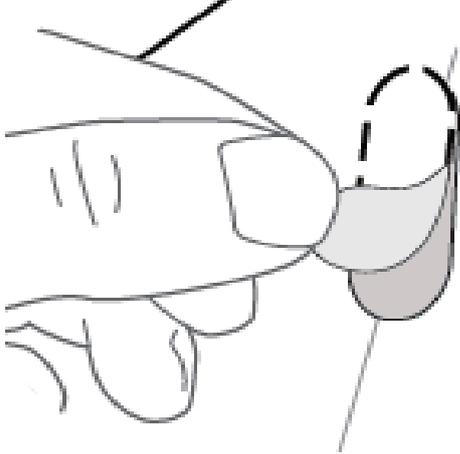


Step 6: TURN the card OVER showing the back of the card.

LOCATE capsule to remove.  
BEND the card as shown  
(see Figure G).

Note: Bending the card helps raise the oval perforated cardboard.

Figure H – Back of the blister card

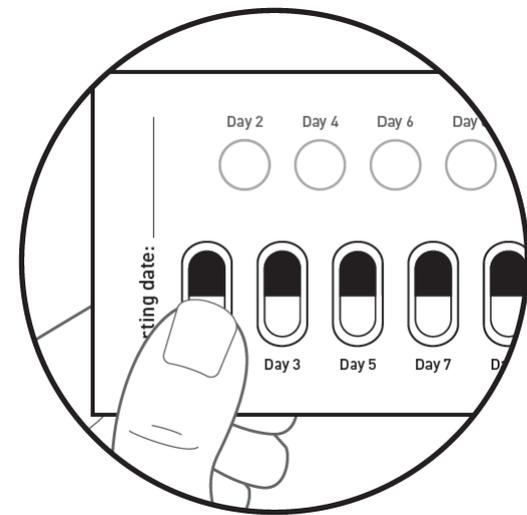


Step 7: REMOVE the oval perforated cardboard (see Figure H).



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

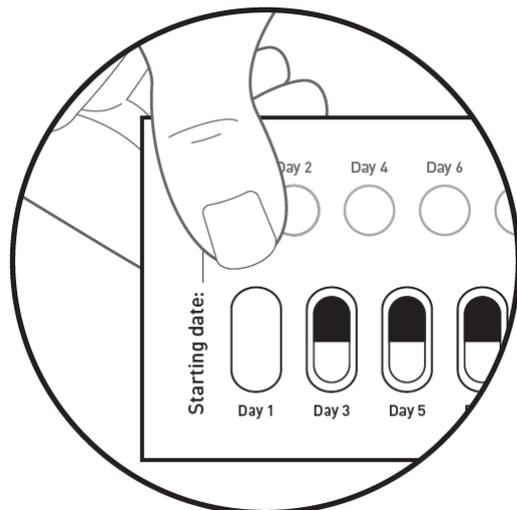
Figure I – Front of the blister card



Step 8: TURN the card OVER showing the front of the card.

PUSH the capsule out (see Figure I).

Figure J – Front of the blister card



Step 9: On the next day, move to the perforated white cardboard circle on the top row labelled Day 2.

Press down on the white cardboard circle removing it (see Figure J).

Note: Removing this white circle will help you remember which day you do not take the medicine.

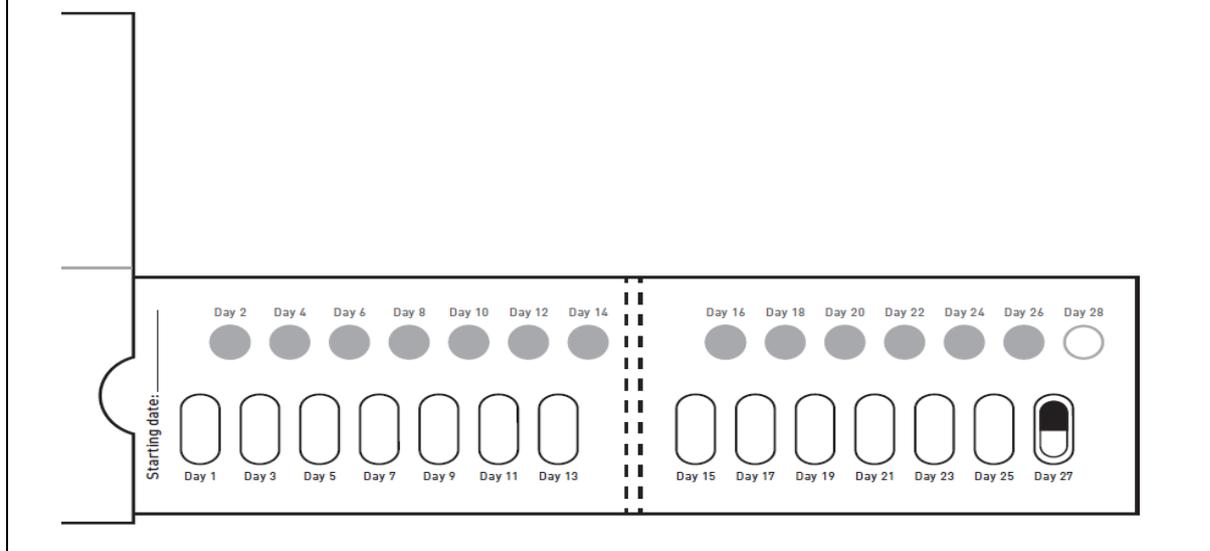
Take 1 Galafold capsule every **other** day.

Close package and store after each use.

After Day 2, move to Day 3 on the blister card.

Alternate daily between taking the capsule and pushing out the perforated white cardboard circles, up to and including day 28.

Figure K – Front of the unfolded blister card



#### **If you take more Galafold than you should**

If you take more capsules than you should, then you should stop taking the medicine and contact your doctor. You may get a headache and feel dizzy.

#### **If you forget to take Galafold**

If you forget to take your capsule at the usual time but remember later, you can take the capsule only if it is within 12 hours of your normal dosing time. If more than 12 hours has passed you should resume taking Galafold at the next planned dosing day and time according to your every other day dosing schedule. Do not take two capsules to make up for your missed dose.

#### **If you stop taking Galafold**

Do not stop taking this medicine without talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Very common:** may affect more than 1 in 10 people

- Headache

**Common:** may affect up to 1 in 10 people

- Palpitations (the feeling of a pounding heart)
- Sensation of spinning (vertigo)
- Diarrhoea
- Feeling sick (nausea)
- Stomachache
- Constipation
- Dry mouth
- Sudden need to defecate
- Indigestion (dyspepsia)
- Tiredness
- Raised levels of creatine phosphokinase in blood tests
- Weight gain
- Muscle spasms
- Muscle pain (myalgia)
- Painful stiff neck (torticollis)
- Tingling in extremities (paraesthesia)
- Dizziness
- Reduced sense of touch or sensation (hypoesthesia)
- Depression
- Protein in the urine (proteinuria)
- Shortness of breath (dyspnoea)
- Nose bleed (epistaxis)
- Rash
- Persistent itch (pruritus)
- Pain

**Uncommon:** may affect up to 1 in 100 people

- Sudden swelling of skin or mucous membrane (e.g. lip, tongue, eye, etc) or both (angioedema)

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

### **5. How to store Galafold**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Galafold contains**

- The active substance is migalastat. Each capsule contains migalastat hydrochloride equivalent to 123 mg migalastat
- The other ingredients are:  
Capsule contents: Pregelatinised starch (maize) and magnesium stearate  
Capsule shell: Gelatin, titanium dioxide (E171), and indigo carmine (E132)  
Printing ink: Shellac, black iron oxide, and potassium hydroxide

### **What Galafold looks like and contents of the pack**

Opaque, blue, and white hard capsules, marked with “A1001” in black ink, size 2 hard capsule (6.4x18.0 mm) containing white to pale brown powder.

Galafold is available in a blister pack containing 14 capsules.

### **Marketing Authorisation Holder**

Amicus Therapeutics UK Limited  
One Globeside  
Fieldhouse Lane  
Marlow  
Buckinghamshire  
SL7 1HZ

### **Manufacturer**

Almac Pharma Services (Ireland) Limited  
Finnabair Industrial Estate  
Dundalk, Co. Louth  
A91 P9KD  
Ireland

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