

Galafold® migalastat 123 mg Hard Capsules

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Galafold?

Galafold contains the active ingredient migalastat. Galafold is used for the long-term treatment of Fabry disease in adults and adolescents aged 12 years and older who have certain genetic mutations (amenable mutations).

For more information, see Section [1. Why am I using Galafold?](#) in the full CMI.

2. What should I know before I use Galafold?

Do not use if you have ever had an allergic reaction to Galafold or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Galafold?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Galafold and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Galafold?

Take one capsule every other day at the same time of the day. Swallow the capsule whole.

Take the GALAFOLD capsule on an empty stomach. Do not consume food or caffeine at least 2 hours before and 2 hours after taking Galafold to give a minimum 4 hours fast.

More instructions can be found in Section [4. How do I use Galafold?](#) in the full CMI.

5. What should I know while using Galafold?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, pharmacist or nurse you visit that you are using Galafold.• Tell your doctor if you have any kidney problems.• Use effective birth control while taking Galafold.
Things you should not do	<ul style="list-style-type: none">• Do not take Galafold if you are also receiving enzyme replacement therapy.• Do not take Galafold if you are allergic to migalastat or any of the other ingredients in Galafold.• Do not take this medicine if you are breast-feeding, until you have spoken with your doctor, pharmacist, or nurse.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Galafold affects you.• No specific studies have been conducted to assess the direct effect of Galafold on the ability to drive and use machines.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol while using this medicine.
Looking after your medicine	<ul style="list-style-type: none">• Keep your capsules in the pack until it is time to take them.• Keep your capsules in a cool dry place where the temperature stays below 30°C.

For more information, see Section [5. What should I know while using Galafold?](#) in the full CMI.

6. Are there any side effects?

Very common side effect that may affect more than 1 in 10 people includes: headache. Common side effects that may affect up to 1 in 10 people include: constipation, depression, diarrhoea, dizziness, dry mouth, feeling sick (nausea), incorrect dose administered, indigestion (dyspepsia), muscle pain (myalgia), muscle spasms, nose bleed (epistaxis), pain, painful stiff neck (torticollis), palpitations (the feeling of a pounding heart), persistent itch (pruritus), protein in the urine (proteinuria), raised levels of creatine phosphokinase in blood tests, rash, reduced sense of touch or sensation (hypoesthesia), sensation of spinning (vertigo), shortness of breath (dyspnoea), stomach ache, sudden need to pass stools, tingling in extremities (paraesthesia), tiredness, and weight gain. Serious side effects include: depression, high blood pressure (systolic hypertension), low blood sugar (hypoglycaemia), memory changes, liver injury, chest pain (musculoskeletal chest pain), overdose, palpitations (the feeling of a pounding heart), sharp or clear vision reduced, or abnormal central or peripheral vision, or night vision effected (visual acuity reduced), and shortness of breath (dyspnoea).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Galafold[®] Hard Capsules (Gal-a-fold)

Active ingredient(s): *migalastat*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Galafold. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Galafold.**

Where to find information in this leaflet:

1. [Why am I using Galafold?](#)
2. [What should I know before I use Galafold?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Galafold?](#)
5. [What should I know while using Galafold?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using Galafold?

Galafold contains the active ingredient migalastat.

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

Fabry disease is caused by the lack of or a faulty enzyme called alpha-galactosidase A (α -Gal A). Depending upon the kind of mutation (change) in the gene that produces α -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) 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 should I know before I use Galafold?

Warnings

Do not use Galafold if:

- you are allergic to migalastat, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any kidney problems.
- are also receiving enzyme replacement therapy.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. There is very limited experience with the use of this medicine in pregnant women. It is not recommended to use Galafold during pregnancy. While taking Galafold you should use effective birth control.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not yet known whether this medicine passes into human breast milk. Your doctor will decide whether you need to stop breast-feeding or temporarily stop your medicine.

Fertility

It is not yet known if this medicine affects fertility in both men or women. If you are planning to have a baby, ask your doctor for advice.

Children and adolescents

This medicine is not suitable for adolescents aged 12 years to < 18 years and weighing < 45 kg. This medicine has not been studied in children under the age of 12 years; therefore, the effects in this age group are not known and use is not recommended.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

4. How do I use Galafold?

How much to take / use

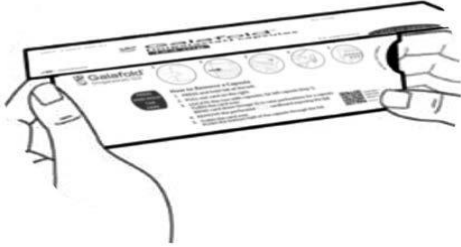

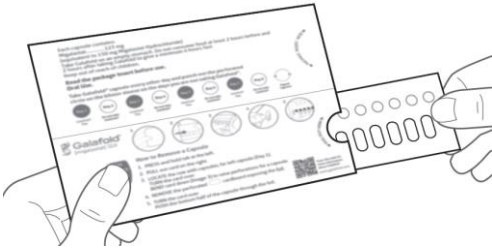
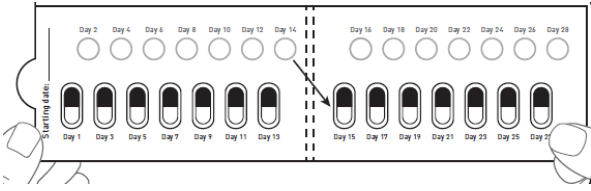
- Take one capsule every other day at the same time of the day.
- DO NOT take Galafold daily.
- Follow the instructions provided and use Galafold until your doctor tells you to stop.

When to take / use Galafold

- Take the GALAFOLD capsule on an empty stomach. Do not consume food or caffeine at least 2 hours before and 2 hours after taking Galafold to give a minimum 4 hours fast. Food and caffeine may interfere with the absorption of the medicine. A minimum of 4 hours fasting-around taking your medicine is needed to allow your medicine to be fully absorbed.

- Water (plain, flavoured, 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.

How to remove a capsule

<p>Figure A</p> 	<p>Step 1. Remove the adhesive seal holding the cover.</p> <p>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 left 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 right side 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 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.

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

Figure E – Front of the blister card

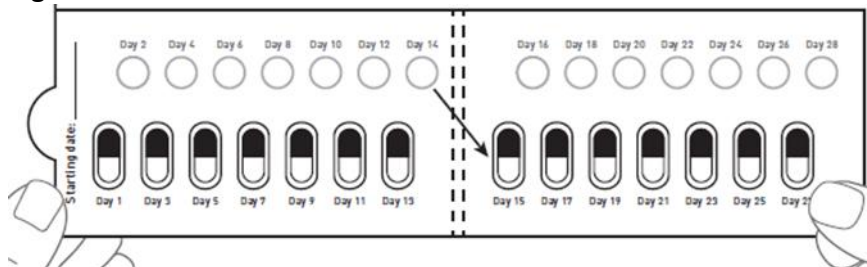
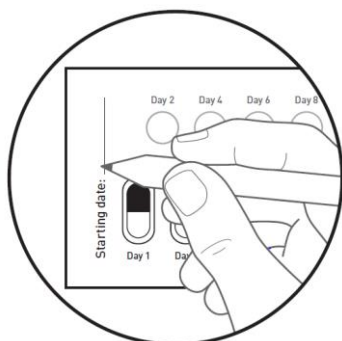
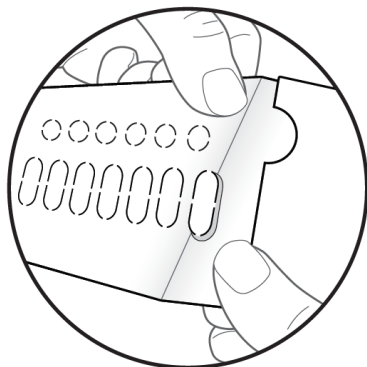


Figure F – Front of the blister card



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).

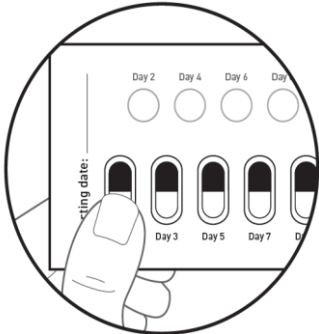
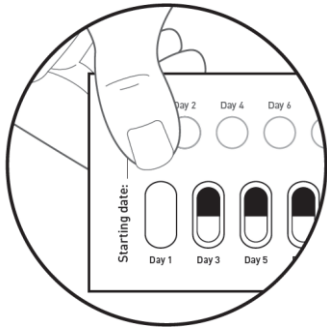
Note: Bending the card helps raise the oval perforated cardboard.

Figure H – Back of the blister card



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

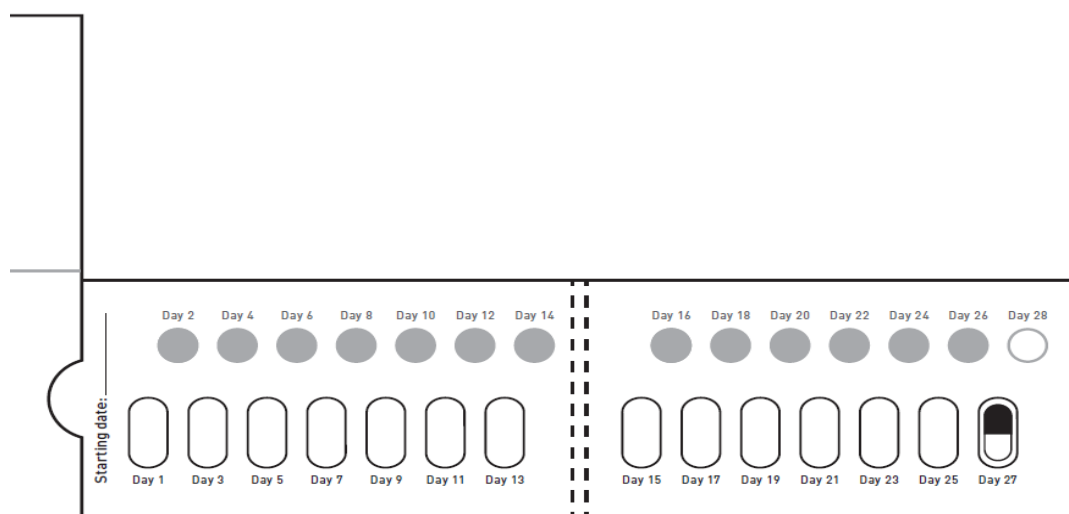
Note: After removing the cardboard, the white backing of the foil may be present, which is ok.

<p>Figure I – Front of the blister card</p> 	<p>Step 8. TURN the card OVER showing the front of the card.</p> <p>PUSH the capsule out</p> <p>(See Figure I).</p>
<p>Figure J – Front of the blister card</p> 	<p>Step 9. On the next day, remove the perforated white cardboard circle on the <u>top row</u> labelled Day 2.</p> <p>Press down on the white cardboard circle removing it (See Figure J).</p> <p>Note: Removing this circle will help you remember which day you do not take the medicine.</p> <p>Take 1 GALAFOLD capsule every other day.</p> <p>Close package and store after each use.</p>

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 forget to use Galafold

Galafold should be used regularly at the same time every other day.

If you miss your dose and it is more than 12 hours since your normal scheduled time, you should take your dose on the next planned dosing day and time according to the every other day dosing schedule.

If you miss your dose at the scheduled time but it is within 12 hours, take your dose.

Do not take a double dose to make up for the dose that you missed.

If you use too much Galafold

If you think that you have used too much Galafold, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia or by calling 0800 764 766 in New Zealand),
- contact your doctor, or pharmacist, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Galafold?

Things you should do

Keep all of your doctor's appointments so your progress can be checked.

Your doctor may want to do some blood and other tests from time to time to check on your progress and to check for any unwanted side effects.

Call your doctor straight away if you:

- Do not feel well while you are taking Galafold. Remind any doctor, dentist, pharmacist, or nurse you visit that you are using Galafold.

Things you should not do

- Do not stop using this medicine suddenly without talking to your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Galafold affects you.

No specific studies have been conducted to assess the direct effect of Galafold on the ability to drive and use machines.

Drinking alcohol

Tell your doctor if you drink alcohol while taking Galafold.

Looking after your medicine

- Keep your capsules in the pack until it is time to take them. If you take the capsules out of the pack, they may not keep well.
- Keep your capsules where the temperature stays below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot see and reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>More broad or affecting different parts of the body:</p> <ul style="list-style-type: none"> • dizziness • feeling sick (nausea) • fever • flu-like illness • frequent daytime urination • headache • incorrect dose administered • increased sense of touch or sensation (hyperaesthesia) • inflammation in parts of the body • insomnia • migraine • nosebleed (epistaxis) • pain • reduced sense of touch or sensation (hypoesthesia) • runny nose (rhinorrhea) • sensation of spinning (vertigo) • sleepiness • swelling • tiredness <p>Muscle or pain-related:</p> <ul style="list-style-type: none"> • aching or radiating pain in back and sides below the ribs and above pelvis (flank pain) • balance concerns • muscle pain (myalgia) • muscle spasms • muscle twitching • painful stiff neck (torticollis) • tingling in extremities (paraesthesia) • tremor <p>Gastrointestinal related:</p> <ul style="list-style-type: none"> • change in bowel habits • constipation • decreased appetite • diarrhoea • dry mouth • indigestion (dyspepsia) • stomachache • sudden need to pass stools • vomiting • weight gain • weight loss 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Skin related: <ul style="list-style-type: none"> inflamed skin (erythema) persistent itch (pruritus), including eye area radiation related skin injury rash sweating Laboratory blood test-related: <ul style="list-style-type: none"> abnormal liver test decreased levels of calcium decreased levels of white blood cells protein in urine (proteinuria) raised level of bilirubin raised levels of creatine phosphokinase raised levels of cholesterol 	
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Serious side effects

Serious side effects	What to do
More broad or affecting different parts of the body: <ul style="list-style-type: none"> depression high blood pressure (systolic hypertension) low blood sugar (hypoglycaemia) memory changes liver injury chest pain (musculoskeletal chest pain) overdose palpitations (the feeling of a pounding heart) sharp or clear vision reduced, or abnormal central or peripheral vision, or night vision effected (visual acuity reduced) shortness of breath (dyspnoea) sudden swelling of skin or mucous membrane (eg, lip, tongue, eye, etc) or both (angioedema) 	Call your doctor straight away, if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience,

- In Australia, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems.

- In New Zealand, you can report side effects to New Zealand Pharmacovigilance Centre at <https://nzphvc.otago.ac.nz/reporting/>.
- By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Galafold contains

Active ingredient	123 mg migalastat equivalent to 150 mg migalastat hydrochloride
Other ingredients	Capsule contents: Pregelatinised maize starch and magnesium stearate Capsule shell: Gelatin, titanium dioxide, and indigo carmine Printing ink: Shellac, iron oxide black, and potassium hydroxide

Do not take this medicine if you are allergic to any of these ingredients.

What Galafold looks like

Galafold 123 mg migalastat hard capsule is opaque blue, and white hard capsules, marked with "A1001" in black ink, containing white to pale brown powder.

A blister pack size containing 14 hard capsules. (Aust R 276051)

Who distributes Galafold

In Australia:

Amicus Therapeutics Pty Ltd
Level 10, 20 Martin Place
Sydney, NSW 2000
Australia

In New Zealand:

Pharmacy Retailing NZ Ltd t/a Healthcare Logistics
58 Richard Pearse Drive Airport Oaks Auckland

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This leaflet was prepared in Sep 2024.