PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Galafold 123 mg

Hard capsules

Each hard capsule contains the **active ingredient**:

Migalastat 123 mg (as migalastat hydrochloride 150 mg). The list of inactive and allergenic ingredients is detailed in section 6.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

The medicine is intended for adults and adolescents aged 16 years and older with certain genetic changes (mutations).

1. WHAT IS THE MEDICINE INTENDED FOR?

Galafold 123 mg is intended for the long-term treatment of adults and adolescents aged 16 years and older, with a confirmed diagnosis of Fabry disease (impaired alpha-galactosidase A enzyme activity) and who have "amenable mutations".

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient migalastat or to any of the additional ingredients contained in the medicine (see section 6 in the leaflet).

Special warnings regarding use of the medicine:

Before treatment with Galafold 123 mg, tell your doctor if you are currently taking enzyme replacement therapy. Do not use Galafold 123 mg if you are currently receiving enzyme replacement therapy.

While you are being treated with Galafold 123 mg, every 6 months your doctor will monitor your medical condition and whether the medicine is working. If your condition worsens, your doctor may perform an additional evaluation or may stop your treatment with Galafold 123 mg.

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/1.73 m^2).

Children and adolescents

This medicine has not been studied in children and adolescents under the age of 16 years; therefore, there is no established safety and efficacy data in these age groups.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist about it. This is because certain other

medicines may increase or decrease the amount of medicine in your body.

Use of the medicine and food

Take the medicine on an empty stomach.

Do not eat for at least two hours before taking the medicine and two hours after taking the medicine.

Pregnancy, breastfeeding and fertility

Pregnancy

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

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

Breastfeeding

Do not use this medicine during breastfeeding without first consulting with your doctor. It is not yet known whether this medicine passes into breast milk. Your doctor will decide whether you should stop breastfeeding or temporarily stop taking the medicine, considering the benefit of breastfeeding to the baby and the benefit of Galafold to the mother.

Fertility in men

It is not yet known if this medicine impairs fertility in men. The effect of Galafold 123 mg on fertility in humans has not been studied yet.

Fertility in women

It is not yet known whether this medicine impairs fertility in women.

If you are planning to have a baby, consult with your doctor, pharmacist, or nurse.

Driving and using machines

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

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor’s instructions.

Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally:

Swallow one capsule intermittently (every other day) at the same hour of the day. Do not take Galafold 123 mg on two consecutive days.

Take the medicine on an empty stomach.

Do not eat for at least two hours before taking the medicine and two hours after taking the medicine.

These 4 hours of fasting around the time of taking the medicine are required to allow full absorption of the medicine.

During the fasting period, you can drink clear liquids, including carbonated drinks.

Do not exceed the recommended dose.

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

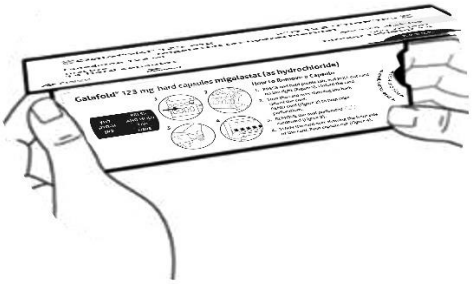
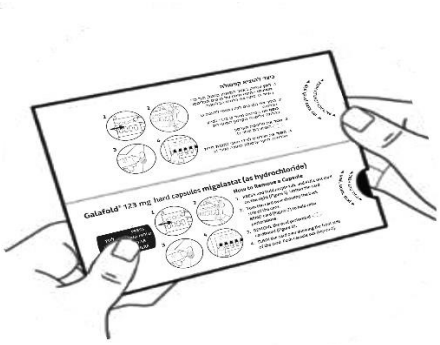
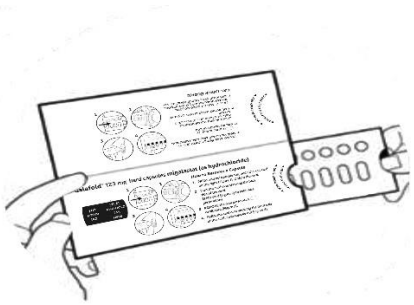
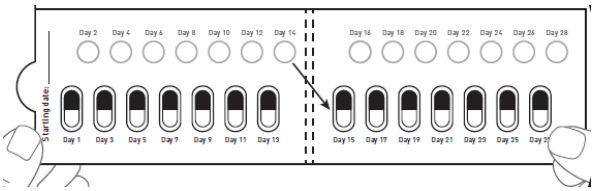
Figure A  	Step 1: Remove the adhesive seal holding the cover. Lift the cover of your Galafold carton (see Figure A).
Figure B – Opened carton  	Step 2: Press and <u>continue holding down the purple tab with your thumb</u> at the **left** side of the carton (see Figure B), and continue to Step 3.
Figure C 	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).

Figure D – Front of the blister card



Step 4: Unfold the blister card
(see Figure D).

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

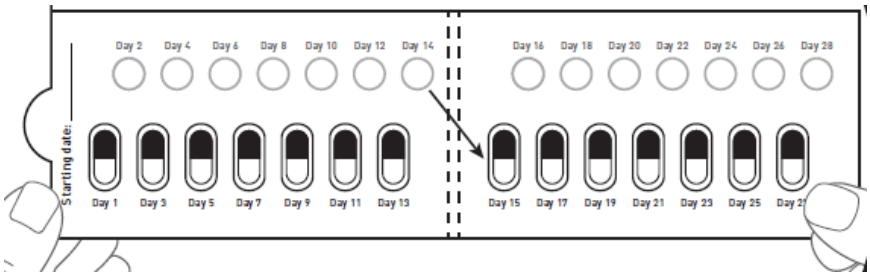
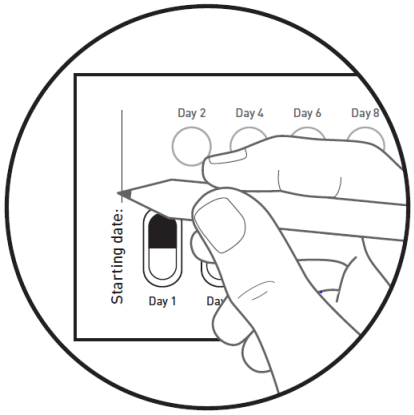


Figure F – Front of the blister card



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).

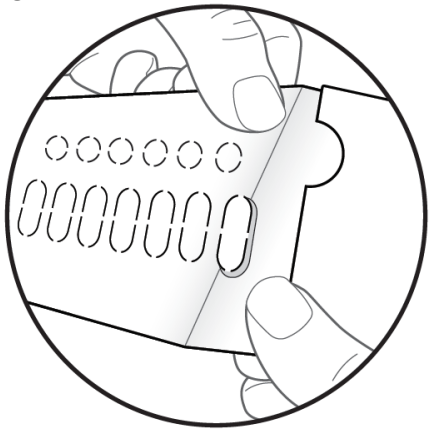
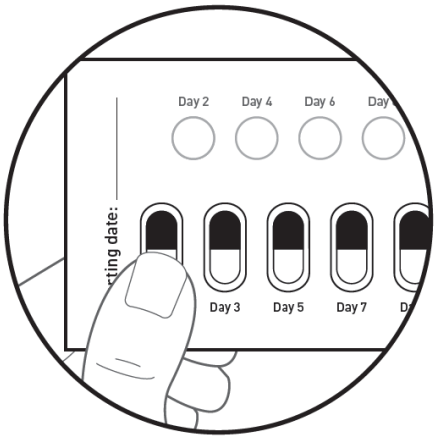
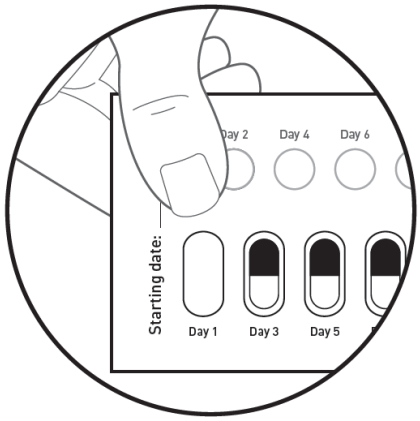
Figure G – Back of the blister card 	Step 6: <u>TURN</u> the card <u>OVER</u> showing the <u>back of the card</u>. LOCATE capsule to remove. BEND the card as shown (see Figure G). Note: <u>Bending</u> the card <u>helps raise</u> the oval perforated cardboard.
Figure H – Back of the blister card 	Step 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 <u>top row</u> labelled Day 2.

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

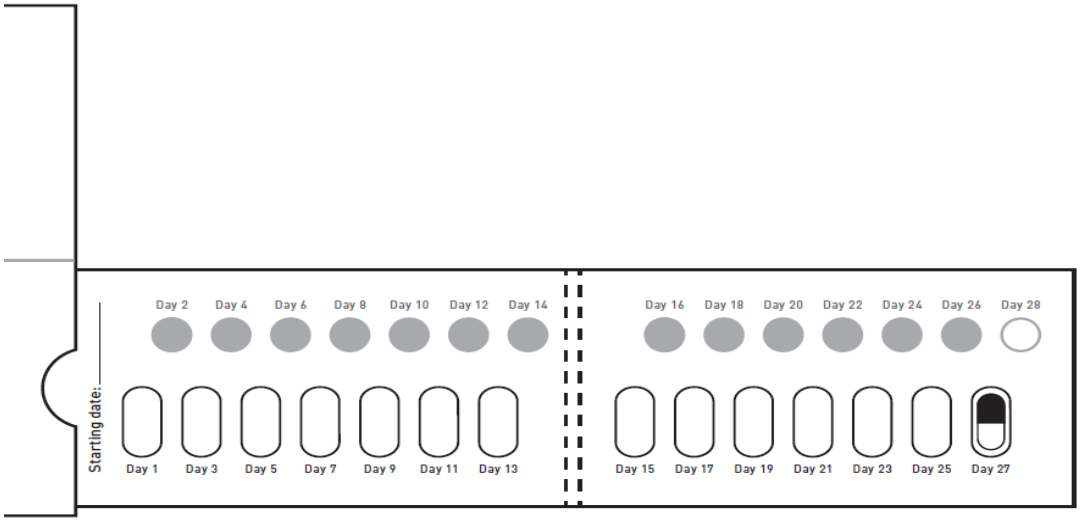
Note: Removing this white circle will help you remember which day you do not take the medicine.

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



Tests and follow up

While you are being treated with Galafold 123 mg, every 6 months your doctor will monitor your medical condition and whether the medicine is working. If your condition worsens, your doctor may perform an additional evaluation or may stop your treatment with Galafold 123 mg.

If you accidentally took a higher dosage, stop taking the medicine and consult with your doctor. You may experience a headache or dizziness.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

If you forgot to take this medicine at the required time, but you remembered later on, the medicine can only be taken within 12 hours of the usual administration time.

If more than 12 hours have elapsed, take the medicine on the next scheduled day, at the time that the medicine is usually taken.

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

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting with the doctor.

If you stop taking the medicine

Do not stop taking the medicine before you discuss the consequences with your doctor.

Do not take medicines in the dark!

Check the label and the dose <u>each time</u> you take medicine.

Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

<u>4. SIDE EFFECTS</u>

As with any medicine, use of Galafold 123 mg may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Very common side effects (effects that may affect more than 1 user out of 10)

- Headache

Common side effects (effects that may affect up to 1 user out of 10)

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

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

https://sideeffects.health.gov.il/

Side effects can also be reported to TrueMed Ltd. Through this report, you are helping to collect safety information about the medicine.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Do not store above 25°C. Do not store in a refrigerator or freezer.
- Store in the original package to protect from moisture.

Do not discard medicines in the wastewater or waste bin. Ask the pharmacist how to dispose of medicines no longer in use.

These measures will help protect the environment.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains:
  Capsule contents:
  Pregelatinised starch and magnesium stearate
  Capsule shell:
  Gelatin, titanium dioxide and indigotine - FD&C Blue 2
  Ink:
  Shellac, black iron oxide, and potassium hydroxide
- What the medicine looks like and the contents of the package:
  Hard capsules, with an opaque blue cap and an opaque white body. The capsules are marked with "A1001" in black ink and are packaged in trays (blisters). Each package contains 14 capsules.
- Registration Holder and address:
  TrueMed Ltd., Israel
  10 Beni Gaon St., Poleg Industrial Park
  P.O.Box 8105, South Netanya 4250499

- Manufacturer and address:
  Amicus Therapeutics UK Ltd., Buckinghamshire, United Kingdom
- Revised in August 2022 according to MOH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:
  158-80-35012-00

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