

# GLIMET TABLETS

Glimepiride / Metformin Hydrochloride (1mg / 500mg , 2mg / 1000mg)

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## What GLIMET is used for

GLIMET is used as an adjunct to diet and exercise in non-insulin dependent diabetes mellitus (NIDDM) (Type 2) patients who are unable to achieve sufficient sugar control with monotherapy of Metformin or Glimepiride alone or who are already treated with the combination of Metformin and Glimepiride as separate tablets.

## How GLIMET works

GLIMET contains medicines called Glimepiride and Metformin hydrochloride.

Glimepiride is an oral glucose-lowering drug of the sulphonylureas class, which acts by increasing the release of insulin from the pancreatic beta cells. This results in opening of calcium channels & increase in intracellular calcium. Thus insulin level is increased.

Metformin, a biguanides class, reduces the output of glucose from the liver and thus reduces the requirement of insulin at the level of liver.

Thus, sulphonylureas and biguanides have additive action. Moreover, Metformin and Glimepiride are often co prescribed in clinical practice, and have proven to be efficacious in achieving the target glycemic control and also in preventing the multiple metabolic defects, which are often present in diabetic subjects.

## Before you use GLIMET

### - When you must not use it

Do not take GLIMET if:

- You are allergic (hypersensitive) to:
  - Glimepiride.
  - Other sulphonylureas (medicines used to lower your blood sugar such as glibenclamide).
  - Sulfonamides (medicines for bacterial infections such as sulfamethoxazole).
  - Metformin.
  - Any of the other ingredients.
- An allergic reaction can include a rash, itching or shortness of breath.
- You have insulin dependent diabetes (type 1 diabetes mellitus).
- You have or had serious problems with your diabetes in the past called diabetic ketoacidosis (a complication of diabetes when your acid level is raised in your body and you may have some of the following signs: fatigue, lose weight quickly, feeling sick (nausea/ vomiting), frequent urination and muscular stiffness).
- You are in a diabetic coma.
- You have recently had a heart attack or any other heart problems.
- You have severe circulation problems or difficulty in breathing.
- You have recently had a severe infection, injury or trauma (shock).
- You have liver or kidney problems
- You are dehydrated.
- You are going to have an X-ray where you will be injected with a dye.
- You are a heavy drinker of alcohol (more than 21 units a week for a man or 14 units a week for a woman). A unit is equivalent to a small glass of wine, one shot or half a pint of beer.
- You are pregnant, planning to get pregnant or are breast-feeding.
- You have severely reduced kidney function.
- You have lactic acidosis [too much lactic acid in the blood (see "Risk of lactic acidosis" below)] or ketoacidosis. Ketoacidosis is a condition in which substances called 'ketone bodies' accumulate in the blood and which can lead to diabetic pre-coma. Symptoms of acidosis may include stomach pain,

abnormal breathing and drowsiness (if severe).

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking GLIMET.

### *Pregnancy and lactation*

Do not take GLIMET if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take GLIMET if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

### - Before you start use it

You must tell your doctor or pharmacist if you:

- Are recovering from an injury, operation, infections with fever, or from other forms of stress, inform your doctor as temporary change of treatment may be necessary.
- Have a severe liver or kidney disorder.
- Are elderly.
- Are on a very low calorie diet (less than 1000 calories a day) or are fasting. This could increase the chances of you getting a very rare, but serious side effect called lactic acidosis.

### *Risk of lactic acidosis*

GLIMET may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration, liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease). If any of the above apply to you, talk to your doctor for further instructions.

Stop taking GLIMET for a short time if you have a condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhoea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.

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Stop taking GLIMET and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma.

Symptoms of lactic acidosis include:

- Vomiting.
- Stomach ache (abdominal pain).
- Muscle cramps.
- A general feeling of not being well with severe tiredness.
- Difficulty in breathing.

Lactic acidosis is a medical emergency and must be treated in a hospital.

During treatment with GLIMET, your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or if you have worsening kidney function.

## - Taking other medicines

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

The following medicines can increase the blood sugar lowering effect of GLIMET. This can lead to a risk of hypoglycaemia (low blood sugar):

- Other medicines to treat diabetes mellitus (such as insulin)
- Medicines to treat pain and inflammation (phenylbutazone, azopropazone,
- oxyphenbutazone, aspirinlike medicines).
- Medicines to treat urinary infections (such as some long acting sulfonamides).
- Medicines to treat bacterial and fungal infections (tetracyclines, chloramphenicol, fluconazole, miconazole, quinolones, clarithromycin).
- Medicines to inhibit blood clotting (coumarin derivatives such as warfarin).
- Medicines supporting muscle build up (anabolics).
- Medicines used for male sex hormone replacement therapy.
- Medicines to treat depression (fluoxetine, MAO inhibitors).
- Medicines lowering high cholesterol level (fibrates).

- Medicines lowering high blood pressure (ACE inhibitors).
- Medicines called anti-arrhythmic agents used to control abnormal heart beat (disopyramide).
- Medicines to treat gout (allopurinol, probenecid, sulfinpyrazone).
- Medicines to treat cancer (cyclophosphamide, ifosfamide, trofosfamide).
- Medicines used to reduce weight (fenfluramine) Medicines to increase circulation when given in a high dose intravenous infusion (pentoxifylline).
- Medicines to treat nasal allergies such as hay fever (tritoqualine).
- Medicines called sympatholytics to treat high blood pressure, heart failure, or prostate symptoms.

The following medicines may decrease the blood sugar lowering effect of GLIMET. This can lead to a risk of hyperglycaemia (high blood sugar level):

- Medicines containing female sex hormones (oestrogens, progestogens).
- Medicines to treat high blood pressure called thiazide diuretics (water tablets).
- Medicines used to stimulate the thyroid gland (such as levothyroxine).
- Medicines to treat allergies and inflammation (glucocorticoids).
- Medicines to treat severe mental disorders (chlorpromazine and other phenothiazine derivatives).
- Medicines used to raise heartbeat, to treat asthma or nasal congestion, coughs and colds, used to reduce weight, or used in life-threatening emergencies (adrenaline and sympathomimetics).
- Medicines to treat high cholesterol level (nicotinic acid).
- Medicines to treat constipation when they are used long term (laxatives).
- Medicines to treat fits (phenytoin).
- Medicines to treat nervousness and sleep problems (barbiturates).
- Medicines to treat increased pressure in the eye (azetazolamide).
- Medicines to treat high blood pressure or lowering blood sugar (diazoxide).

- Medicines to treat infections, tuberculosis (rifampicine).
- Medicines to treat severe low blood sugar levels (glucagon).

The following medicines can increase or decrease the blood sugar lowering effect of GLIMET:

- Medicines to treat stomach ulcers (called H2 antagonists).
- Medicines to treat high blood pressure or heart failure such as beta-blockers, clonidine, guanethidine and reserpine.
- These can also hide the signs of hypoglycaemia, so special care is needed when taking these medicines.

GLIMET can affect the way some other medicines work. Also, some medicines can affect the way GLIMET works.

- Medicines for high blood pressure (hypertension) such as water tablets (diuretics), ACE inhibitors (such as enalapril).
- Medicines for asthma such as salbutamol or formoterol (beta-2-agonists).
- Medicines used for inflammation called steroids.
- Medicines inhibiting blood clotting (coumarin derivatives such as warfarin).

## How to use GLIMET

### - How much to use

The dose of GLIMET depends on your needs, condition and results of blood and urine sugar tests and is determined by your doctor. Do not take more tablets than your doctor has prescribed. The usual starting dose is one tablet once a day.

If necessary, your doctor may increase the dose after each 1 - 2 weeks of treatment.

The maximum recommended dose in adults is 6 mg Glimepiride and 3000 mg Metformin per day.

When switching from combination therapy of Glimepiride plus Metformin as separate tablets.

GLIMET should be administered on the basis of dosage currently being taken.

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Your dose of GLIMET may need to be adjusted if you change weight, change your lifestyle, or if you are under a lot of stress. Please speak to your doctor if any of these situations apply to you.

If you feel the effect of your medicine is too weak or too strong do not change the dose yourself, but ask your doctor.

## - When to use it

- Take this medicine by mouth once or twice daily before or with meals meal as directed by your doctor or pharmacist.
- It is preferred to start just before or with the first main of the day (usually breakfast). If you do not have breakfast, you should take the product on schedule as prescribed by your doctor.
- It is important not to leave out any meal when you are on GLIMET. Taking GLIMET with food lowers the chance of getting an upset stomach due to the metformin component.
- Try to take your medicine at the same time each day so that it becomes part of your daily routine.

## - How long to use it

- Keep taking GLIMET until your doctor tells you to stop. Do not stop taking GLIMET just because you feel better. If you stop your illness may get worse.
- If you interrupt or stop the treatment, you should be aware that the desired blood sugar lowering effect is not achieved or that the disease will get worse again. Keep taking GLIMET until your doctor tells you to stop.
- If you have any further questions on the use of this product, ask your doctor or pharmacist.

## - If you forget to use it

It is important to take your GLIMET tablet regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. In that case, just carry on with the next dose as normal. Do not take a double dose to make up for a forgotten dose.

## - If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your

nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Because of the Glimepiride component, the hypoglycaemia may happen if you take too much GLIMET and therefore you should instantly consume enough sugar (e.g. a small bar of sugar cubes, sweet juice atau sweetened tea) and inform a doctor immediately.

Because of the Metformin component, the following effects may happen if you take too much GLIMET: unexpected weight loss, feeling very sick or being very sick, very fast breathing which you cannot stop, stomach pains or feeling cold. You may have something called lactic acidosis. The doctor may use a method called 'haemodialysis' to remove the extra lactate and metformin from your body.

## While you are using it

### - Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists that are treating you that you are taking GLIMET.
- Tell your doctor immediately if you become pregnant while taking this medication.

### - Things you must not do

- Do not stop taking your medicine unless your doctor tells you to.
- Do not take any new medicines without consulting your doctor.
- Do not give GLIMET to anyone else, even if they have the same symptoms or condition as you.

### - Things to be careful of

#### Alcohol Consumption

Be careful how much alcohol you drink. This is because the combined effect of GLIMET and alcohol can make you sleepy.

#### Driving and using machines

Your tablets may make you feel sleepy. Do not drive or use any tools or machines without talking to your doctor first.

## Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

### Side effects of Glimepiride:

- Allergic reactions (including inflammation of blood vessels, often with skin rash) which may develop into serious reactions with difficulty in breathing, fall in blood pressure and sometimes progressing to shock.
- Abnormal liver function including yellowing of the skin and eyes (jaundice), problems with the bile flow (cholestasis), inflammation of the liver (hepatitis) or liver failure.
- Allergy (hypersensitivity) of the skin such as itching, rash, hives and increased sensitivity to sun. Some mild allergic reactions may develop into serious reactions.
- Severe hypoglycaemia including loss of consciousness, seizures or coma.

### Side effects of Metformin:

The most severe side effect associated with Metformin is lactic acidosis (build up of lactic acid in the blood).

Early symptoms of lactic acidosis may be nonspecific consisting of:

- Nausea.
- Vomiting.
- Abdominal pain.
- Diarrhoea.

Other reactions include:

- Megaloblastic anemia.
- GI symptoms (diarrhea, vomiting etc).
- Sensitivity reactions such as rash, urticaria and pruritis may occur.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Tell your doctor if you get any side effect that bothers you or that does not go away.

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You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Public → Reporting Medicinal Problems / Side Effects (ConSERF) or Vaccine (AEFI)).

## Storage and Disposal of GLIMET

### - Storage

- Store below 30°C.
- Protected from light & moisture.

### - Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## Product Description

### - What it looks like

**GLIMET 1MG / 500MG  
SUSTAINED RELEASE TABLETS:**

White to off white flat oblong shaped uncoated tablet having one blue round inlay tablet near the center of one side.

**GLIMET 2MG / 1000MG  
SUSTAINED RELEASE TABLETS:**

White to off white flat oblong shaped uncoated tablet having one pink round inlay tablet near the center of one side.

### - Ingredients

Active ingredients:

- Metformin Hydrochloride USP.
- Glimepiride USP.

Inactive ingredients:

- Lactose Monohydrate.
- Ammonia Methacrylate copolymer Type B.
- Methylene Chloride.
- Acetone.
- Hydrogenated Castor Oil.
- Magnesium Stearate.
- Starch.
- Lake of Brilliant Blue.
- Polyvinyl Pyrrolidone.
- Sodium Starch Glycolate.
- Colloidal Silicon Dioxide.
- Magnesium Stearate.
- Purified Water.

### - MAL number(s):

**GLIMET 1MG / 500MG**

**SUSTAINED RELEASE TABLETS:**

MAL14120019AZ

**GLIMET 2MG / 1000MG**

**SUSTAINED RELEASE TABLETS:**

MAL14120018AZ

## Manufacturer

Torrent Pharmaceuticals Limited

Indrad 382 721, Tal: Kadi,

City: Indrad, Dist. Mehsana,

India

## Product Registration Holder

Laboratories Torrent (Malaysia) Sdn. Bhd.

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18/05/2020

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