

GLYMET F.C. TABLET

Glibenclamide/Metformin Hydrochloride (5/500mg)

What is in this leaflet

1. What Glymet is used for
2. How Glymet works
3. Before you use Glymet
4. How to use Glymet
5. While you are using it
6. Side effects
7. Storage and Disposal of Glymet
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Glymet is used for

It is used to treat type 2 diabetes. It is used along with diet and exercise.

How Glymet works

Glymet is a sulfonylurea and biguanide antidiabetic combination. The sulfonylurea works by causing the pancreas to release insulin, which helps to lower blood sugar levels. The biguanide works by decreasing the amount of sugar that the liver produces and the intestines absorb. It also helps to make your body more sensitive to the insulin that you naturally produce.

Before you use Glymet

- When you must not use it

If you are allergic to the following:

- metformin hydrochloride (e.g. Glucophage)
 - glibenclamide (e.g. Daonil)
 - any other sulfonylurea medicine such as gliclazide (e.g. Diamicron), glipizide (e.g. Minidiab), glimepiride (e.g. Amaryl,) or any other sulphonamides.
 - any of the ingredients listed at the end of this leaflet.
- Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not take Glymet :

- If you have severely reduced kidney function.

- If 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).

If you are currently taking miconazole (eg. Daktarin), either orally or as a mouth gel.

Taking Glymet with miconazole may cause an excessive drop in your blood glucose level.

If you have the following conditions:

- type I diabetes mellitus also known as insulin dependent diabetes
- type II diabetes that is already well controlled by diet alone
- serious complications with your diabetes or diabetic ketoacidosis (a symptom of uncontrolled diabetes, in which substances called ketone bodies accumulate in the blood - you may notice this as an unusual fruity odour on your breath)
- severe liver disease
- kidney failure or severe kidney disease
- dehydration (for instance due to persistent or severe diarrhoea or recurrent vomiting), severe blood loss or shock
- severe infection or gangrene
- certain heart or blood vessel problems, including a recent heart attack or heart failure (when the heart fails to pump blood effectively)
- severe breathing difficulties
- alcohol dependence or binge drinking
- porphyria, an inherited disorder
- glucose and galactose malabsorption syndrome or lactase deficiency.

Pregnancy and lactation

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

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

- Before you start to use it

Risk of lactic acidosis

Glymet 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 Glymet 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.

Stop taking Glymet 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 Glymet, 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

Some medical conditions may interact with Glymet. Tell your doctor or pharmacist if you have any medical conditions, especially if any of the following apply to you:

- if you have allergies to medicines, foods, or other substances
- if you have had a severe allergic reactions (eg, a severe rash, hives, itching, breathing difficulties, dizziness) to any other sulfonamide medicine, such as acetazolamide, celecoxib, certain diuretics (eg, hydrochlorothiazide), glipizide, probenecid, sulfamethoxazole, or zonisamide
- if you have heart failure, especially heart failure that is treated by medicine
- if you have a history of heart problems (eg, a heart attack, heart failure), blood vessel problems, lung or breathing problems, thyroid problems, stomach or bowel problems (eg, a blockage, paralysis), adrenal gland or pituitary problems, or lactic acidosis
- if you have vomiting, diarrhea, poor health or nutrition, low blood calcium or vitamin B₁₂ levels, or anemia
- if you or a family member have a condition called glucose-6-phosphate dehydrogenase (G6PD) deficiency
- if you have an infection, fever, recent injury, or moderate to severe burns
- if you drink alcohol or have a history of alcohol abuse
- if you will be having surgery or certain lab procedures
- if you take a beta-blocker (eg, propranolol)

- **Taking other medicines**

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

Examples of medicines that may affect the way Glymet works:

- Other medicines containing metformin or glibenclamide
- Other medicines used to treat diabetes
- Diuretics, also called fluid tablets
- Iodinated contrast agents (dyes)
- Certain antifungal medicines such as miconazole
- Certain antibiotics including medicines used to treat tuberculosis.
- Medicines used to treat high blood pressure and heart conditions (eg, calcium channel blocking drugs)
- Non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation including arthritis, such as aspirin
- Phenytoin (Dilantin), a medicine used to treat epilepsy (fits or seizures)
- Medicines used to treat depression such as monoamine oxidase inhibitors (MAOIs)
- Medicines used to treat schizophrenia and mental illnesses, such as phenothiazines
- Estrogens and progestagens in hormone replacement therapy and oral contraceptives
- Thyroid hormones, such as thyroxine
- Medicines used to treat for ulcers and reflux, such as ranitidine (e.g. Zantac)
- Certain medicines used to treat gout such as probenecid

How to use Glymet

- **How much to use**

Your doctor will prescribe a dose of Glymet that is effective for you and that you can tolerate. This will usually not exceed the maximum recommended daily dose of 20mg glibenclamide/ 2000mg metformin. Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not

understand the instructions on the label, ask your doctor or pharmacist for help.

- **When to use it**

Take Glymet by mouth with meals.

- **How long to use it**

Continue taking *Glymet* for as long as your doctor recommends.

- **If you forget to use it**

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed 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.

Taking too many tablets may cause you to feel sick, tired, vomit, have trouble breathing, unusual muscle pain, stomach pain or diarrhea. These may be early signs of a serious condition called lactic acidosis (build up of lactic acid in the blood). You may also experience symptoms of hypoglycaemia (low blood glucose). If not treated quickly, these symptoms may progress to loss of co-ordination, slurred speech, confusion, fits or loss of consciousness.

If you do experience any signs of hypoglycaemia, raise your blood glucose quickly by eating sweets, sugar or honey, drinking a non-diet soft drink or taking glucose tablets.

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 treating you that you are taking *Glymet*.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not use any other medicines containing metformin or glibenclamide, in the form of either a single or a combination product, while you are being treated with *Glymet*.

Do not skip meals while taking *Glymet*.

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *Glymet* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, *Glymet* 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:

Some of the side effects are:
Diarrhea, mild stomach pain, nausea, stomach upset, vomiting, poor appetite, metallic taste, skin rash, visual disturbances, symptoms of liver disease (eg. Yellowing of the eyes or skin (jaundice) and dark coloured urine), frequent infections (fever, chills, sore throat or mouth ulcers) and hypoglycemia.

Signs of hypoglycemia including weakness, trembling or shaking, sweating, light headedness, headache, dizziness, irritability and tearfulness

Tell your doctor immediately or go to accident and emergency at the nearest hospital if you notice any of the following symptoms of lactic acidosis (buildup of acid in the blood):

- nausea, vomiting, stomach pain
- trouble breathing
- feeling weak, tired or generally unwell
- unusual muscle pain
- sleepiness
- dizziness or light headedness
- shivering, feeling extremely cold
- slow heartbeat.

Lactic acidosis is a very rare but serious side effect requiring urgent medical attention or hospitalisation. although rare, if lactic acidosis does occur, it can be fatal. The risk of lactic acidosis is higher in the elderly, those whose diabetes is poorly controlled, those with prolonged fasting, those with certain heart conditions, those who drink alcohol and those with kidney or liver problems.

You may report any side effects or adverse drug reactions directly to the National Centre for adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of *Glymet*

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

- 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

Glymet 5/500 is a yellow coloured biconvex oblong tablet with the trademark “e” on one side and scoreline & ‘03’ on the other side.

- Ingredients

Active ingredients

Each *Glymet* 5/500mg F.C. Tablet contains:

- Metformin Hydrchloride 500mg
- Glibenclamide 5mg

- Inactive ingredients

AEROSIL, Microcrystalline Cellulose, Magnesium stearate, lactose monohydrate, Ferric oxide yellow, Sepifilm, Purified Water, Polyplasdone , Povidone K 30

- MAL number:

MAL06121092AZ

Manufacturer

Glymet 5/500:
Orient Pharma Co. Ltd.
No 8, Kehu 1st Road, Huwei Township, Yunlin County 632, Taiwan

Product Registration Holder

Orient Europharma (M) Sdn Bhd. E-08 Garden Shoppe, One City Jalan USJ 25/1C, 47650 Subang Jaya Selangor Malaysia

Date of revision

30/06/2023

Serial number

NPRA(R2/1)211111/783.