GLYPRIDE TABLET

Glimepiride(1mg, 2mg)

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What Glypride is used for

Glypride is used to treat a non-insulin dependent (Type II) diabetes mellitus (NIDDM) when diet, physical exercise and weight reduction alone, have not been able to control your blood sugar levels. Glypride is also indicated for use in combination with insulin to lower blood glucose in patients with (Type II) diabetes whose high blood sugar levels cannot be controlled with diet and exercise in conjuction with an oral hypoglycemic agent (a drug used to lower blood sugar levels) alone.

How Glypride works

Glypride is an orally active blood sugar lowering drug. This drug belongs to a blood sugar lowering group of medicines called sulfonylurea. Glypride works by increasing the amount of insulin released from your pancreas. The insulin then lowers your blood sugar levels.

Before you use Glypride

When you must not use it

- If you are allergic (hypersensitive) to Glypride or other sulfonylureas (medicines used to lower your blood sugar such as glibenclamide) or sulfonamides (medicines for bacterial infections such as sulfamethoxazole) or any of the other ingredients of Glypride tablets.
- If you have insulin dependent diabetes [(Type I) Diabetes mellitus]
- If you have 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, feeling sick (nausea), frequent urination and muscular stiffness)
- If you are in a diabetic coma.
- If you have severe kidney disease.

• If you have severe impairment of liver disease

Before you start use it

Please speak with your doctor if you notice any of the adverse effects or any undesired effects or unexpected changes. Since some adverse effects (e.g., severe hypoglycaemia, certain changes in the blood picture, severe allergic or pseudoallergic reactions, or liver failure) may under certain circumstances become life-threatening, it is essential that, if sudden or severe reactions do occur, you inform a doctor at once, and on no account continue taking the drug without a doctor's express guidance.

Pregnancy and breastfeeding:

Glypride should not be used during pregnancy or if you are breast feeding. Make sure your doctor knows if you are breast feeding, pregnant, or think you might be pregnant. Your doctor may want you to use insulin during this time.

Taking other medicines

- Ask your doctor or pharmacist before taking, taking or recently taken any other medicine, including over-the counter products.
- Avoid drinking alcohol while you are taking this medicine.
- There are various drugs that can interact with Glypride and change the way the medicine works. Some of these drugs are acetylsalicylic acid such as Aspirin, "sulfa" drugs, warfarin and beta- blockers.
- Some medicines can make it harder for you to control your diabetes. These include ACE inhibitors (i.e. drugs used to treat high blood pressure-hypertension), diuretics (water pills), corticosteroids (such as
- prednisone), and birth control pills.

Make sure your doctor and pharmacist knows if you are taking these or any other medicines.

How to use Glypride

How much to use

The usual initial dose is 1 mg glimepiride once daily. If necessary; the daily dose can be increased. Any increase should be based on regular blood sugar monitoring, and should be gradual, i.e., at intervals of one to two weeks, and carried out stepwise, as follows: 1 mg-2mg-3 mg-4mg- 6 mg and - in exceptional cases - 8 mg.

The usual dose range in patients with well controlled diabetes is 4mg daily. Only some patients benefit from daily doses of more than 6 mg.

Take exactly as prescribed by your doctor. Follow the directions on your prescription label.

When to use it

Glypride is usually taken once a day with breakfast or the first main meal of the day. Follow your doctor's instructions. Glypride must be swallowed without chewing.

Take glypride tablets every day at around the same time. Choose a time that is easy to remember.

Use as directed by your doctor or pharmacist.

How long to use it

The duration of treatment is not limited. It is important to continue taking Glypride for as long as your doctor prescribes it in order to lower the blood glucose level.

If you forget to use it

Consult your doctor or pharmacist on what you should do 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)

Glypride overdose may lead to severe and sometimes life-threatening hypoglycaemia and may require hospitalisation even as a precautionary measure.

Significant overdose with severe reactions is a medical emergency and

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will necessitate immediate treatment and hospitalisation. Mild episodes of hypoglycaemia can usually be treated with oral carbohydrates. Adjustments in dosage, meal patterns or physical activity may be necessary.

While you are using it

Things you must do

Inform your doctor if you have Low blood sugar (hypoglycemia):

- If your blood sugar gets too low, you may feel shaky, weak, drowsy, confused, or very hungry. You may sweat or have blurred vision, a fast heartbeat, trouble concentrating, or a headache that doesn't go away. Signs of severe hypoglycemia include disorientation, loss of consciousness and seizures.
- You may have low blood sugar while you are taking glypride, especially if you miss a meal, exercise for a long time, drink alcohol or use another antidiabetic medication with Glypride.

In exceptional stress situations (e.g., trauma, surgery, and infections with fever) blood sugar control may deteriorate, and a temporary change to insulin may be necessary.

Things you must not do

Avoid drinking alcohol. It lowers blood sugar and may interfere with your diabetes treatment. Avoid exposure to sunlight or tanning beds. Glypride can make you sunburn more easily. Wear protective clothing and use sunscreen (SPF 30 or higher) when you are outdoors.

Things to be careful of

When you begin treatment with this medication, you should not perform tasks which may require special attention (for example, driving an automobile or operating dangerous machinery) until you know how you tolerate your medicine.

Driving and using machines

Low or high blood sugar levels may impair alertness and reactions, especially when beginning or after altering treatment or when Glypride is not taken regularly. This may affect the ability to drive or to operate machinery.

Side effects

As with any type of medication, Glypride is associated with some side effects. It may, however, affect different people in different ways. Just because side effects have occurred in other people does not mean you will get them

If you have problems with these side effects, talk with your doctor or pharmacist:

- Mild nausea or vomiting
- Dizziness
- Low blood sugar (hypoglycemia), see above.
- This medicine may make your skin sensitive to sunlight and could cause a rash or sunburn. Use a sunscreen when outdoors.

Call your doctor right away if you have any of these side effects:

- Unexplained fever, chills or sore throat
- Unusual bleeding or bruising
- Yellowing of skin or eyes, dark colored urine or light-coloured bowel movements
- Skin rash or hives

This is not a complete list of side effects. For any unexpected effects while taking Glypride, tell your doctor or pharmacist.

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 portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Clopilet

Storage

Store below $25^{\circ}\mathrm{C}$ in a cool dry place, protected from light

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

Glypride 1mg Tablet: A white biconvex, uncoated caplet tablet with breakline on one side and plain on other side.

Glypride 2mg Tablet: A yellow biconvex, uncoated caplet tablet with breakline on one side plain on other side.

Ingredients

Active ingredient

Glimepiride

Inactive ingredients

Lactose, cellulose- microcrystalline, Magnesium stearate, sodium starch glycolate, purified water.

MAL numbers:

Glypride 1mg tablet: MAL07010954A Glypride 2mg tablet: MAL07010956A

Manufacturer

Sun Pharmaceutical Industries Limited Survey No.259/15, Dadra-396 191, U.T. of Dadra & Nagar Haveli, INDIA.

Product Registration Holder

Pahang Pharmacy Sdn. Bhd Lot 5979, Jalan Teratai, 5 1/2 Mile Off Jalan Meru 41050 Klang Selangor, MALAYSIA.

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