

GLIMETOR TABLET

Glimepiride Tablets 2 mg USP

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What Glimetor is used for

Glimetor contains Glimepiride. It is used to treat a certain form of diabetes (type 2 diabetes mellitus) when diet, physical exercise and weight reduction alone have not been able to control your blood sugar levels.

How Glimetor works

Glimetor belongs to a group of medicines called sulfonylureas. It works by increasing the amount of insulin released from your pancreas. The insulin then lowers your blood sugar levels.

Before you use Glimetor

- When you must not use it
- If you have known hypersensitivity to the drug or other sulfonylureas or sulfonamides or any of the excipients of the product.
- If you have diabetic ketoacidosis (condition where chemical balance of the body becomes far too acidic), with or without coma. This condition should be treated with insulin.
- If you have Insulin Dependent Diabetes
- If you have kidney or liver function disorder, in case of severe kidney or liver function

disorder, a change over to insulin is required.

- Before you start to use it
Check with your doctor or pharmacist before taking your medicine 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
 - You have a severe liver or kidney disorder. If you are not sure if any of these apply to you, talk to your doctor or pharmacist before taking Glimetor.
 - Glimetor use is associated with increased cardiovascular mortality as compared to treatment with diet alone or diet plus insulin. Before taking Glimetor consult your doctor for potential risks and advantages of Glimetor tablets and of alternative models of therapy
 - Glimetor must be taken shortly before or during a meal. When meals are taken at irregular hours or skipped altogether, treatment with glimepiride may lead to hypoglycaemia (low blood sugar).

Lowering of the haemoglobin level and breakdown of red blood cells (haemolytic anemia) can occur in patients missing the enzyme glucose-6-phosphate dehydrogenase (G6PD).

The information available on the use of Glimepiride in people under 18 years of age is limited. Therefore, its use in these patients is not recommended.

- Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other

medicines, including medicines obtained without a prescription. Your doctor may wish to change your dose of Glimetor if you are taking other medicines, which may weaken or strengthen the effect of Glimetor on the level of sugar in your blood.

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

- Other medicines to treat diabetes mellitus (such as insulin or metformin)
- Medicines to treat pain and inflammation (phenylbutazone, azopropazone, oxyphenbutazone, aspirin like 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, sulfapyrazone)
- Medicines to treat cancer (cyclophosphamide, ifosfamide, trofosfamide)

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- 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 Glimetor. 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 heart beat, 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 (rifampicin)
- Medicines to treat severe low blood sugar levels (glucagon)

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

- 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.

Glimetor may either increase or weaken the effects of the following medicines:

- Medicines inhibiting blood clotting (coumarin derivatives such as warfarin)

How to use Glimetor

How much to use

The dose of Glimetor 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 Glimetor 1 mg tablet once a day
- If necessary, your doctor may increase the dose after each 1 - 2 weeks of treatment
- The maximum recommended dose is 6 mg Glimetor per day
- A combination therapy of glimepiride plus metformin or of glimepiride plus insulin may be started. In such a case your doctor will determine the

proper doses of glimepiride, metformin or insulin individually for you

- Your dose of Glimetor 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, just before or with the first main meal 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 Glimetor
- Swallow the tablets whole with at least half glass of water. Do not crush or chew the tablets

How long to use it

Glimetor should be used every day to work properly. If you stop using Glimetor, your blood sugar may go up. Talk to your doctor before stopping this treatment.

If you forget to use it

If you forget to take a dose, do not take a double dose to make up for forgotten doses.

If you use too much (overdose)

If you happen to have taken too much Glimetor or an additional dose there is a danger of hypoglycaemia (Lower blood sugar) and therefore you should instantly consume enough sugar (e.g. a small bar of sugar cubes, sweet juice, sweetened tea) and inform a doctor immediately.

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When treating hypoglycaemia due to accidental intake in children, the quantity of sugar given must be carefully controlled to avoid the possibility of producing dangerous hyperglycaemia (Increased blood sugar). Persons in a state of unconsciousness must not be given food or drink.

Since the state of hypoglycaemia may last for some time it is very important that the patient is carefully monitored until there is no more danger. Admission into hospital may be necessary, also as a measure of precaution. Show the doctor the package or remaining tablets, so the doctor knows what has been taken.

Severe cases of hypoglycaemia accompanied by loss of consciousness and coma are cases of medical emergency requiring immediate medical treatment and admission into hospital. It may be helpful to tell your family and friends to call a doctor immediately if this happens to you.

While you are using it

- Things you must do

Tell your doctor if

- Glimetor should not be taken during pregnancy. Tell your doctor if you are, you think you might be or are planning to become pregnant.
- Glimetor may pass into breast milk. Glimetor should not be taken during breast feeding.

- Things you must not do

You must not leave out any meal when you are on Glimetor

- Things to be careful of

Driving and using machines

Your ability to concentrate or react may be reduced if your blood sugar is lowered (hypoglycaemia), or raised (hyperglycaemia) or if you develop visual problems as a result of such conditions. Bear in mind

that you could endanger yourself or others (e.g. when driving a car or using machines). Please ask your doctor whether you can drive if you:

- have frequent episodes of hypoglycaemia,
- have fewer or no warning signals of hypoglycaemia

Taking Glimepiride with Alcohol

Alcohol intake may increase or decrease the blood sugar lowering action of Glimepiride in an unpredictable way.

Side effects

Like all medicines, Glimetor 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.

- 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

Some patients experienced the following side effects whilst taking Glimetor:

Rare side effects

- Lower blood sugar than normal (hypoglycaemia)
- Decrease in the number of blood cells:
 - Blood platelets (which increases risk of bleeding or bruising).
 - White blood cells (which makes infections more likely).
 - Red blood cells (which can make the skin pale and cause weakness or breathlessness).

These problems generally get better after you stop taking Glimetor

Very rare side effects

- Feeling or being sick, diarrhoea, feeling full or bloated, and abdominal pain
- Decrease in the amount of sodium level in your blood (shown by blood tests)
- Problems with your sight may occur when beginning treatment with Glimetor. This is due to changes in blood sugar levels and should soon improve
- Increased liver enzymes

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please 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).

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Storage and Disposal of Glimetor

Date of revision

19/03/2014

- Storage

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

GLIMETOR 2 MG TABLETS
Yellow coloured, oval shaped, biconvex, uncoated tablets with break line on one side and plain on other side

- Ingredients

- Active ingredient

Glimepiride

- Inactive ingredients

Lactose Monohydrate

Starch (Maize Starch)

Ferric Oxide Yellow

Polyvinyl pyrrolidone (K-30)

Purified Water

Sodium starch glycolate

Hydrophobic colloidal anhydrous silica

Magnesium Stearate

- MAL number(s):

MAL12125047A

Manufacturer

TORRENT

PHARMACEUTICALS LTD.

Indrad 382 721, District: Mehsana

INDIA.

Product Registration Holder

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