

GLIMIN

Glipemiride 2mg

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WHAT GLIMIN TABLETS IS USED FOR:

Glimin 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 GLIMIN TABLETS WORKS:

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

BEFORE YOU TAKE GLIMIN TABLETS:

When you must not take it:

- If you are allergic (hypersensitive) to Glimepiride 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 Glimin.
- If you have insulin dependent diabetes (type 1 diabetes mellitus)

- 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)
- You are in a diabetic coma
- You have severe kidney disease
- You have a severe liver disease

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

Before you start to take 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 Glimin.

The information available on the use of Glimin 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 Glimin if you are taking other medicines, which may weaken or strengthen the effect of Glimin on the level of sugar in your blood.

The following medicines can increase the blood sugar lowering effect of Glimin. 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, miconazole, quinolones)
- 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 (probenecid, sulfapyrazone)
- 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 Glimin. 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 (corticosteroids)
- 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 (acetazolamide)
- Medicines to treat high blood pressure or antidote for low sugar level caused by too high level of insulin in the body (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 Glimin:

- 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

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

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

Taking Glimin with food and drink

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

HOW TO TAKE GLIMIN TABLETS

In principle, the dosage of Glimepiride is determined by the desired blood glucose level. The dosage of Glimepiride must be the lowest which is sufficient to achieve the desired metabolic control.

Treatment with Glimepiride must be initiated and monitored by a doctor. Glimepiride must be taken at the times and in the doses prescribed. During treatment with Glimepiride glucose levels in blood and urine must be measured regularly. In addition, it is recommended that regular determinations of the proportion of glycated haemoglobin be carried out.

How much to use

Initial dose and titration

The usual initial dose is 1mg Glimepiride once daily.

If necessary the daily dose can be increased. It is recommended that the increase be guided by regular blood glucose monitoring and that the dose be increased gradually i.e. at intervals of one to two weeks and according to the following dose steps: 1mg-2mg-3mg-4mg-6mg. Daily doses of more than 6mg are more effective only in minority of patients. A maximum of 8mg day may not be exceeded.

Dose range in patient with well controlled diabetes:

Usual daily doses in patient with well controlled diabetes are 1 to 4 mg Glimepiride.

Distribution of doses:

Timing and distribution of doses are to be decided by the physician, taking into consideration the patient's current lifestyle.

Normally a single daily dose of Glimepiride is sufficient.

Secondary dosage adjustment:

An improvement in the control of diabetes is associated with higher insulin sensitivity therefore Glimepiride requirement may fall as treatment proceeds. To avoid hypoglycaemia, dose reduction or cessation of Glimepiride therapy must therefore be considered in time. Correction of dosage must also be considered whenever the patient's weight changes, the patient's lifestyle changes or other factors arise which cause an increased susceptibility to hypoglycaemia or hyperglycaemia (refer to "Special Precautions").

Changes-over from other oral antidiabetics to Glimepiride:

There is no exact dosage relationship between Glimepiride and other oral antidiabetics. When substituting Glimepiride for other oral antidiabetics, it is recommended that the procedure be the same as for initial dosage, starting with daily doses of 1mg. This applies even in case where the patient is being switched from the maximum dose of another oral antidiabetic.

When to use it

It is recommended that this dose be taken immediately before a substantial breakfast or-if none is taken-immediately before the first main meal. It is very important not to skip meals after the tablet(s) have been taken.

How long to use it

Treatment with Glimepiride is normally long-term therapy.

If you forget to use it

If a patient forgets to take a dose, this must never be corrected by subsequently taking a larger dose. Measures for dealing with such situations (in particular forgetting a dose or skipping a meal) where a dose cannot be taken at the prescribed time must be discussed and agreed between physician and patient beforehand.

If you use too much (overdose)

If it is discovered that too high a dose or an extra dose of Glimpiride has been taken, a physician must be notified immediately.

WHILE YOU ARE USING IT***Things you must do******Important information about hypoglycaemia (low blood sugar)***

When you take Glimin, you may get hypoglycaemia (low blood sugar). Please see below for additional information about hypoglycaemia, its signs and treatment.

Following factors could increase the risk of you getting hypoglycaemia:

- Undernourishment, irregular meal time, missed or delayed meal or period of fasting
- Changes to your diet
- Taking more Glimin than needed
- Having kidneys that do not work properly
- Having severe liver disease
- If you suffer from particular hormone-induced disorders (disorders of the thyroid glands, of the pituitary gland or adrenal cortex)
- Drinking alcohol (especially when you skip a meal)
- Taking certain other medicines (See Taking other medicines above)
- If you increase the amount of exercise you do and you don't eat enough food or eat food containing less carbohydrate than usual.

Signs of hypoglycaemia include:

- Hunger pangs, headache, nausea, vomiting, sluggishness, sleepiness, problems sleeping, restlessness, aggression, problems with concentration, reduced alertness and reaction time, depression, confusion, problems with your speech and sight, slurred speech, shakiness, partial paralysis, dizziness, helplessness
- The following signs may also occur: sweating, clammy skin, anxiety, fast or increased heart beat, high blood pressure, awareness of your heart

beat, sudden strong pain in the breast that may radiate into neighbouring areas (angina pectoris and cardiac arrhythmias)

If blood sugar levels continue to drop you may suffer from considerable confusion (delirium), develop fits, lose self control, breathing may be shallow and your heart beat slowed down, you may fall into unconsciousness. The clinical picture of a severe reduced blood sugar level may resemble that of a stroke.

Treating hypoglycaemia:

In most cases the signs of reduced blood sugar vanish very quickly when you consume some form of sugar, e.g. sugar cubes, sweet juice, sweetened tea.

You should therefore always take some form of sugar with you (e.g. sugar cubes). Remember that artificial sweeteners are not effective. Please contact your doctor or go to the hospital if taking sugar does not help or if the symptoms recur.

Laboratory Tests

The level of sugar in your blood or urine should be checked regularly. Your doctor may also take blood tests to monitor your blood cell levels and liver function.

Things you must not do***Pregnancy and breast-feeding******Pregnancy***

Glimin should not be taken during pregnancy. Tell your doctor if you are, you think you might be or are planning to become pregnant.

Breast feeding

Glimin may pass into breast milk. Glimin should not be taken during breast feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Things to be careful of***Driving and using machines***

Your ability to concentrate or react may be impaired 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 a car if you:

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

SIDE EFFECTS:

Like all medicines, Glimin Tablets can cause side effects, although not everybody gets them.

Tell your doctor immediately if you experience any of the following symptoms:

- 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 Glimin:

Possible symptoms (rare)

- 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 Glimin

Possible symptoms (very rare)

If you experience any of these symptoms, **tell your doctor immediately**

- 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)

Other side effects include:

- Allergy (hypersensitivity) of the skin may occur such as itching, rash, hives and increased sensitivity to sun. Some mild allergic reactions may develop into serious reactions with swallowing or breathing problems, swelling of your lips, throat or tongue. Therefore in the event of one of these side effects, **tell your doctor immediately**
- Allergic reactions with sulfonylureas, sulfonamides, or related drugs may occur
- Problems with your sight may occur when beginning treatment with Glimin. 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.my (Consumers → Reporting)

STORAGE AND DISPOSAL OF GLIMIN TABLETS

Storage

Keep medicine out of the reach and sight of children.

Store below 25°C.

Do not use Glimin Tablets after the expiry date, which is stated on the carton after 'EXP'. The expiry date refers to the last day of that month.

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

Green colour, oblong shaped with flat surface tablet.

Ingredients

The active substance is Glimepiride.

Each tablet contains 2 mg Glimepiride.

The other ingredients are Alcohol 95%, Povidone, Corn starch, Lactose monohydrate, Yellow (Iron oxide), Brilliant blue FCF Al-lake, Sodium starch glycolate and Magnesium stearate.

MAL No.

MAL07082872A

MANUFACTURER

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PRODUCT REGISTRATION HOLDER

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DATE OF REVISION

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