

Patient Information Leaflet

GLIMEPIRIDE 1mg, 2mg, 3mg and 4mg TABLETS

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

1. What Glimepiride Tablets are and what they are used for
2. Before you take Glimepiride Tablets
3. How to take Glimepiride Tablets
4. Possible side effects
5. Storing Glimepiride Tablets
6. Further Information

1. WHAT GLIMEPIRIDE TABLETS ARE AND WHAT THEY ARE USED FOR

Glimepiride is one of a group of medicines called sulphonylurea hypoglycaemics, which are used for the treatment of diabetes by helping to control blood sugar levels (glucose). Diabetes is a condition where the body does not produce enough insulin to control the level of blood glucose.

Glimepiride Tablets are used to treat non-insulin dependent (Type II) diabetes mellitus, in addition to a recommended diet, regular physical exercise and weight reduction when these have not worked on their own.

2. BEFORE YOU TAKE GLIMEPIRIDE

Do not take Glimepiride Tablets if you:

- are allergic (hypersensitive) to glimepiride, any of the other ingredients (listed in Section 6) or to other oral sulphonylurea anti-diabetics or sulphonamide antibiotics
- have type I insulin-dependent diabetes
- have suffered from confusion, fainting or coma as a result of your diabetes
- have been told by your doctor you have 'ketoacidosis' (your breath may smell of pear drops)
- have severe kidney or liver disease, as your diabetes will need to be treated with insulin
- are pregnant or breastfeeding.

Talk to your doctor or pharmacist before taking the tablets if:

- you are suffering from an infection with or without fever
- you have had a recent accident, are to have an operation or other situation which is stressful to the body
- you are planning to become pregnant
- you have been told by your doctor that you have an intolerance to some sugars. Glimepiride Tablets contain lactose.

Take special care with Glimepiride Tablets

Treatment with Glimepiride Tablets may lead to hypoglycaemia (low blood sugar) when meals are taken irregularly or if meals are missed.

Some of the symptoms of low blood sugar:

- Headache, ravenous hunger, feeling sick, being sick, tiredness, sleep disturbances, restlessness, aggression, difficulty concentrating, depression, confusion, speech or vision disturbances, tremor, partial paralysis, dizziness, helplessness, loss of self control, delirium, convulsions leading to loss of consciousness including coma, rapid or shallow breathing and slowed heart beat.
- You may also experience sweating, clammy skin, anxiety, faster heart beat, increased blood pressure and other heart problems, which if not treated can be serious.
- These symptoms usually disappear quickly after you eat some carbohydrates (especially sugar) but not with artificial sweeteners.

Always contact your doctor if the any of these symptoms occur, as they may come back, even after you take some sugar.

Situations where you are more likely to experience low blood sugar:

- If you do not take your medicine as prescribed or take too much.
- If you do not eat properly or regularly, if you skip meals, or are fasting.
- Changes in the diet.
- An imbalance between physical activity and carbohydrate intake.
- Consumption of alcohol (especially if you also skip meals).
- Reduced kidney function or severe liver problems. Disorders of thyroid or adrenal function.
- If you are taking some other medicines (see the section "Taking other medicines").

Laboratory investigations or tests

If you have to have blood tests or urine tests, you must always tell the person doing the test that you are taking Glimepiride Tablets.

Regular monitoring of the levels of glucose in your blood and urine, haemoglobin levels, white blood cells, and liver enzyme values are required during treatment with Glimepiride Tablets.

Important information about some of the ingredients of Glimepiride Tablets:

Glimepiride 2 mg Tablets contain the colourings tartrazine (E102) and sunset yellow FCF (E110) which may cause allergic reactions.

Do not take Glimepiride Tablets if you have a galactose intolerance, Lapp lactase deficiency or other problems absorbing glucose-galactose as this product contains lactose.

Taking Glimepiride Tablets with food and drink

Glimepiride Tablets must be taken shortly before or during a meal.

Pregnancy and Breastfeeding

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

Do not take Glimepiride Tablets during pregnancy. Tell your doctor if you are planning to become pregnant.

You must not take Glimepiride Tablets if you are breastfeeding.

Driving and using machines

You may feel sleepy or have blurred vision when starting or changing treatment with Glimepiride Tablets; this can also happen if you forget to take your medicine. Do not drive or operate machinery if affected.

You must also be aware of the symptoms of low blood sugar **before driving** (see "Take special care")

Taking Glimepiride Tablets with other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines including those obtained without a prescription.

Some medicines may affect how well Glimepiride Tablets work.

Tell your doctor if you are taking any of the following medicines:

Medicines which may make glimepiride seem more effective and increase the risk of low blood sugar:

- anti-inflammatory medicines (pain killers) such as salicylates, phenylbutazone, azapropazone and oxyfenbutazone
- other anti-diabetic medicines (e.g. insulin, metformin)
- P-amino salicylic acid, used to treat some forms of tuberculosis
- male sex hormones and anabolic steroids
- medicines used to treat gout (e.g. probenecid, sulfinpyrazone and allopurinol)
- antibacterial and antifungal agents such as fluconazole, miconazole, chloramphenicol, quinolones, some sulphonamides, tetracyclines
- anti-coagulants (medicines to thin the blood or stop blood clotting)

Continued overleaf

- medicines containing fenfluramin (diet-pills)
- medicines used to treat blood pressure and heart disease (e.g. ACE inhibitors, and high doses of pentoxifylline)
- fibrates (cholesterol lowering agents)
- anti-depressants (e.g. monoamine oxidase inhibitors, fluoxetine)
- anti-cancer drugs (e.g. cyclophosphamide, ifosfamide and trophosphamide)
- tritoqualine used to treat allergies and skin disorders.

Medicines which may weaken the effect of glimepiride:

- the contraceptive pill, hormone replacement therapy and other medicines containing female hormones
- certain diuretics (water tablets)
- thyroid stimulating agents
- anti-inflammatory agents (glucocorticoids) e.g. prednisolone
- antipsychotic drugs (e.g. chlorpromazine)
- adrenaline; some asthma medicines (e.g. salbutamol and formeterol) decongestants used to treat colds
- nicotinic acid at high doses
- long term use of laxatives
- medicines used to treat epilepsy (e.g. phenytoin)
- diazoxide, used in emergency treatment of high blood pressure or in hypoglycaemia
- glucagon, used to treat episodes of hypoglycaemia
- sleeping pills (e.g. barbiturates)
- rifampicin, used to treat tuberculosis
- acetazolamide, used to treat glaucoma.

Others, which may increase or decrease the effect of glimepiride:

- anti-ulcer medicines (e.g. cimetidine and ranitidine)
- medicines used to treat high blood pressure (e.g. beta-blockers, guanethidine, reserpine and clonidine); these can also hide the signs of low blood sugar so special care is needed when taking these medicines.
- alcohol.

3. HOW TO TAKE GLIMEPIRIDE TABLETS

The basis for successful treatment of diabetes is a healthy diet, regular physical activity, as well as routine checks of blood and urine. It is important to continue with the recommended diet as well as taking Glimepiride Tablets.

Your doctor will decide the right dose for you depending on your condition. Follow your doctor's instructions carefully. Check the pharmacy label and ask your doctor or pharmacist if you're not sure.

Adults including the elderly:

- Take the tablets shortly before or during a substantial breakfast or first main meal.
- Swallow the tablets whole with some liquid.
- The usual starting dose is 1mg glimepiride per day.
- If control is not achieved your doctor may increase your dose by 1mg every 1 to 2 weeks to 2mg, 3mg or 4mg per day.
- The recommended maximum dose is 6mg glimepiride per day.

If you are already taking other oral diabetic agents (such as metformin) or insulin, and your condition is not stable, your doctor may also give you glimepiride tablets, starting at a low dose of 1mg per day and increasing the dose every 1-2 weeks until the required control is achieved.

Your doctor will monitor you carefully when adding other medicines or when changing to or from another anti-diabetic medicine.

Children: Glimepiride Tablets are not recommended in children.

If you forget to take a tablet:

Take another as soon as you remember or wait until the next dose is due then continue as before. Do not take a double dose to make up for a missed dose.

If you take more Glimepiride Tablets than you should:

Contact your doctor immediately or go to your nearest Accident and Emergency department. Take this leaflet, the container and any remaining tablets with you, so that the medical staff know exactly what you have taken.

Symptoms of overdosing are: Feeling sick, being sick and abdominal pain. The hypoglycaemia is in general accompanied by neurological symptoms such as agitation, tremor, vision disturbances, co-ordination problems, sleepiness, coma, and convulsions. Symptoms may occur up to 24hrs after ingestion of Glimepiride Tablets. In general hospitalisation is therefore recommended.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Glimepiride Tablets can cause side effects in some people.

Stop taking the tablets and tell your doctor immediately or go to the nearest hospital casualty department if you notice any of the following side effects:

- An allergic reaction which may cause skin rash. This may very rarely develop into a severe reaction with swelling of the face, lips or tongue, difficulty swallowing or breathing, low blood pressure and shock.

Contact your doctor if you experience any of the following rare or very rare effects:

- Low blood sugar (hypoglycaemia), for symptoms see section 2 "Take special care".
- Changes in the blood, which may cause anaemia, tiredness, unusual bruising, nose bleeds or more frequent infections.
- Liver problems, which may cause yellowing of the skin and whites of eyes.

Other side effects

Uncommon side effects (reported in less than 1 in 100 people):

- Temporary visual disturbances.

Rare side effects (reported in less than 1 in 1000 people):

- Increased liver enzymes.

Very rare side effects (reported in less than 1 in 10,000 people):

- Allergic inflammation of vessels, cross allergy with antibiotics (sulphonamides).
- Nausea, vomiting, diarrhoea, bloating, stomach pain.
- Increased skin sensitivity to sunlight.

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.

5. STORING GLIMEPIRIDE TABLETS

Keep out of the reach and sight of children

Do not store Glimepiride Tablets above 30°C.

Store in the original packaging.

Do not use after the expiry date stated on the carton. Unused tablets should be taken back to the pharmacist for safe disposal.

6. FURTHER INFORMATION

What is in this medicine:

Each tablet contains 1mg, 2mg, 3mg or 4mg of the active ingredient glimepiride.

The other ingredients are lactose monohydrate, sodium starch glycolate (type A), magnesium stearate, microcrystalline cellulose, povidone and the following colourings:

Glimepiride 1 mg Tablets: Red iron oxide (E172)

Glimepiride 2 mg Tablets: Yellow iron oxide (E172), Sunset yellow FCF (E110), tartrazine (E102), brilliant blue FCF (E133)

Glimepiride 3 mg Tablets: Yellow iron oxide (E172)

Glimepiride 4 mg Tablets: Indigo Carmine (E132)

What this medicine looks like and contents of the pack:

Glimepiride Tablets are flat, oblong tablets with bevelled edges, with a score on one side and marked with "G" on the other side. The 1mg tablets are pink, the 2mg tablets are green, the 3mg tablets are yellow and the 4mg tablets are blue.

They are supplied in blister packs of 30 tablets.

Marketing Authorisation Holder:

Strandhaven Limited (T/A Somex Pharma), High Road, Seven Kings, Ilford, Essex, IG3 8BS, UK.

Manufacturer:

Strandhaven Limited (T/A Somex Pharma), High Road, Seven Kings, Ilford, Essex, IG3 8RA, UK.

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