

FLAT DIMENSION = 180 x 560mm
FOLDED DIMENSION = 180 x 35mm

30 mm

10mm

PACKAGE LEAFLET: INFORMATION FOR THE USER

Glimepiride 1mg, 2mg, 3mg and 4mg Tablets glimepiride

Read all of this leaflet carefully before you start taking this medicine, because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Glimepiride Tablets are and what they are used for
2. What you need to know before you take Glimepiride Tablets
3. How to take Glimepiride Tablets
4. Possible Side Effects
5. How to Store Glimepiride Tablets
6. Contents of the pack and other information

1. What Glimepiride Tablets are and what they are used for

- The name of your medicine is Glimepiride 1mg or 2mg or 3mg or 4mg tablets. The active ingredient is Glimepiride
- Glimepiride belongs to a group of medicines called oral sulphonylurea, which helps to control blood sugar levels.
- Glimepiride works by increasing the amount of insulin released from your pancreas. The insulin then lowers your blood sugar levels.
- Glimepiride 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.

2. What you need to know before you take Glimepiride Tablets

Do not take these Tablets if you:

- have ever had an allergic reaction to glimepiride, any of the ingredients (these are listed in Section 6.), other sulphonylureas (e.g. glibenclamide, gliclazide, tolbutamide) or sulphonamides (e.g. sulfamethoxazole). An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- have insulin dependant (type 1) diabetes
- have severe liver or kidney problems.
- have suffered diabetic coma.
- have been told by your doctor that you have ‘ketoacidosis’ (your breath may smell of pear drops).
- 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)

Do not take this medicine if any of the above applies to you. Talk to your doctor or pharmacist before taking glimepiride.

Warnings and Precautions

Talk to your doctor, pharmacist or nurse before taking Glimepiride Tablets 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 problem with your liver or kidneys.

If you are not sure if any of these apply to you, talk to your doctor or pharmacist before taking glimepiride.

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

Important information about hypoglycaemia (low blood sugar)

When you take glimepiride, 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 times, missed or delayed meals or a period of fasting
- Changes to your diet
- Taking more glimepiride 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 medicines
- 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, 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, difficulty digesting, sensory disturbances.
- The following signs may also occur: sweating, clammy skin, anxiety, fast or increased heart beat, high blood pressure, awareness of your heartbeat, 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 severely 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.

Children and adolescents

The use of Glimepiride by children under 18 years of age is not recommended.

Other medicines and Glimepiride tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Your doctor may wish to change your dose of glimepiride if you are taking other medicines, which may weaken or strengthen the effect of glimepiride on the level of sugar in your blood.

Especially the following medicines which are likely to increase or reduce the blood sugar lowering effect of Glimepiride:

The following medicines can increase the blood sugar lowering effect of glimepiride. 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 sulphonamides)
 - Medicines to treat bacterial and fungal infections (tetracyclines, chloramphenicol, fluconazole, miconazole, quinolones, clarithromycin)
 - Medicines to inhibit blood clotting (coumarin derivatives such as warfarin)
 - Medicines to support muscle build up (anabolics)
 - Medicines to treat depression (fluoxetine, MAO-inhibitors)
 - Medicines lowering high cholesterol level (fibrates)
 - Medicines lowering high blood pressure (ACE inhibitors)
 - Medicinal products called anti-arrhythmic agents used to control abnormal heart beat (disopyramide)
 - Medicines to treat gout (allopurinol, probenecid, sulfinpyrazone)
 - 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 blood pressure, heart failure, or prostate symptoms
 - Medicines used to replace male sex hormones
- The following medicines may decrease the blood sugar lowering effect of glimepiride. 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 used 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 constipation when they are used long term (laxatives)
- Medicines used to treat fits (phenytoin)
- Medicines used to treat nervousness and sleep problems (barbiturates)
- Medicines used to treat increased pressure in the eye (acetazolamide)
- Medicines used 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)
- Medicines to treat high cholesterol levels (nicotinic acid)

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

- Medicines for 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 Glimepiride may either increase or weaken the effects of the following medicines.
- Medicines inhibiting blood clotting (coumarin derivatives such as Warfarin)

Colesevelam, a medicine used to reduce cholesterol, has an effect on the absorption of Glimepiride. To avoid this effect, you should be advised to take Glimepiride at least 4 hours before colesevelam.

Glimepiride tablets with food, drink and alcohol

- Alcohol intake may increase or decrease the blood sugar lowering action of glimepiride in an unpredictable way.
- You are advised NOT to drink alcohol with this medicine. Discuss this with your doctor if you have any questions.

Pregnancy, breast-feeding and fertility

- If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine
- Remind your doctor if you are pregnant and diabetic as your blood glucose levels must be closely monitored.

Breastfeeding

Glimepiride can pass into breast milk. Glimepiride should not be used while breastfeeding.

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

Driving and using medicines

Your ability to concentrate or react may be reduced if your blood sugar is lowered (hypoglycaemia) or increased (hyperglycemia), 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

XXXXXX

10mm

SAME SIZE ARTWORK
560 mm x 180 mm

Glimepiride tablets contain Lactose

- If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

Information on sodium content:

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially “sodium-free”.

3. How to take Glimepiride Tablets

- Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- Glimepiride is taken orally, just before the or with the first main meal of the day (usually breakfast). If you do not have breakfast, then you should take the medicine as recommended by your doctor. It is important that you do not miss a meal when taking Glimepiride.
- Swallow the tablets with at least half glass of water. DO not crush or chew the tablets.
- Glimepiride tablets are meant to be taken in addition to following any advice you have been given on diet, exercise and weight loss.
- **You** doctor may prescribe Glimepiride tablets to take in addition to or instead of other diabetes treatments. Follow instructions given by your doctor carefully.
- The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

The recommended dose is

- The usual starting dose is 1 mg each day but this may be increased by your doctor at suitable intervals usually 1-2 weeks and depending on your responses to treatment, up to a maximum dose of 6mg 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 glimepiride 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, must ask your doctor

If you take more Glimepiride tablets than you should

- If you happen to have taken too much glimepiride or an additional dose, there is a danger of hypoglycaemia (for signs of hypoglycaemia, see Section 2- Warnings and precautions) and therefore you should instantly consume enough sugar (e.g. a small amount of sugar cubes, sweet juice, sweetened tea) and inform a doctor immediately. When treating hypoglycaemia due to accidental intake in children, the quantity of sugar must be carefully controlled to avoid the possibility of producing dangerous hyperglycaemia. 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 as a precaution. Show the doctor the leftover pack or tablets so the doctor is able to know what you have taken.

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

If you forget to take Glimepiride Tablets

- If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule.

DO NOT TAKE A DOUBLE DOSE TO MAKE UP FOR THE FORGOTTEN DOSE

If you stop taking this medicine:

- If you interrupt or stop the treatment you should be aware that the desired blood sugar lowering effect is not achieved or that disease will get worse again. Keep taking glimepiride until your doctor tells you to stop. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine may sometimes cause side effects, although not everybody gets them.

Tell your doctor immediately if you experience 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 with problems swallowing or breathing, swelling of your lips, larynx or tongue. Therefore, if any of these side effects occur.

Contact your doctor immediately.

- Severe hypoglycaemia including loss of consciousness, seizures or coma

Some patients experienced the following side effects whilst taking glimepiride:

Rare: may affect up to 1 in 1,000 people

- Lower blood sugar than normal (hypoglycaemia) (See Section 2-Warnings and precautions)
 - 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)
 - Weight gain
 - Hair loss
 - Changes in your sense of taste
- These problems generally get better after you stop taking glimepiride

Very rare: may affect up to 1 in 10,000 people

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

- Liver problems including yellowing of the skin and eyes (jaundice), problems with the bile flow (cholestasis), inflammation of the liver (hepatitis) or liver failure. 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)

Not known: frequency cannot be estimated from the available data

- Decreased levels of platelets in the blood causing a disorder characterised by blood spots, severe unusual bleeding or bruising under the skin (thrombocytopenia purpura),
- Allergic reactions with sulfonylureas, sulfonamides, or related drugs may occur
- Problems with your sight may occur when beginning treatment with glimepiride. This is due to changes in blood sugar levels and should soon improve
- Increased liver enzymes

Tell your doctor if you notice any such symptoms.

- If you notice any of these effects ensure that you immediately take some sugar or carbohydrates. This will help control your symptoms while you go to your doctor or pharmacist.
- To avoid hypoglycaemia do not miss or delay meals or change your diet or take more Glimepiride tablets than needed, or do a more intense or rigorous physical exercise or more work than normal.
- Ask your doctor or pharmacist for more information if you are not sure how to recognise this.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellowcard Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Glimepiride Tablets

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton after {EXP.}. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original package.
- Do not use the tablets after the expiry date shown on the label after EXP. The expiry date refers to the last day of that month
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Glimepiride tablets contain

- The active substance is Glimepiride and each tablet contains 1 mg, 2mg, 3mg or 4mg of the active ingredient Glimepiride.
- The other ingredients are: lactose, sodium starch glycollate, microcrystalline cellulose, colloidal silicon dioxide, povidone and magnesium stearate.

In addition:

- Glimepiride 1mg tablets contain red ferric oxide (E172)
- Glimepiride 2mg and 3mg tablets contain yellow ferric oxide (E172)
- Glimepiride 2mg and 4mg tablets contain indigo carmine lake (E132).

What Glimepiride Tablets look like and contents of pack

- Glimepiride 1mg tablets are pink coloured, elongated with notch in centre, flat bevelled edged, uncoated tablets with “B” and “L” debossed on either side of breakline on one side and only breakline on other side.
- Glimepiride 2mg tablets are green coloured, elongated with notch in center, flat bevelled edged, uncoated tablets with “B” & “L” debossed on either side of breakline on one side & only breakline on other side.
- Glimepiride 3mg tablets are light yellow coloured, elongated with notch in centre, flat bevelled edged uncoated tablets “B” and “L” debossed on either side of breakline on one side and only breakline on other side.
- Glimepiride 4mg tablets are blue coloured, elongated with notch in centre, flat bevelled edged, uncoated tablets with “B” and “L” debossed on either side of breakline on one side and only breakline on other side.
- Glimepiride tablets are available in blister packs of 10, 20, 30 or 60 tablets. Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

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Glimepiride 1mg Tablets; PL 17907/0106

Glimepiride 2mg Tablets; PL 17907/0107

Glimepiride 3mg Tablets; PL 17907/0108

Glimepiride 4mg Tablets; PL 17907/0109

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