accord

Package leaflet: Information for the user

Glimepiride 1 mg Tablets
Glimepiride 2 mg Tablets
Glimepiride 3 mg Tablets
Glimepiride 4 mg 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, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Glimepiride Tablets is and what it is 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 is and what it is used for

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

What Glimepiride Tablets is used for:
Glimepiride Tablets are 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 Glimepiride Tablets and tell your doctor if:
- You are allergic 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 this medicine (listed in section 6).
- 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 this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Glimepiride tablets.

Warnings and precautions
Talk to your doctor or pharmacist 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
- If you have 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 Glimepiride Tablets.
- 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 tablets 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 tablets, 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 Glimepiride tablets than needed
- Having decreased kidney function
- 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 below)
- If you increase your body exercise and you don't eat enough food or eat food containing less carbohydrate than normal

Signs of hypoglycaemia include:
Hunger pangs, headache, nausea, vomiting, sluggishness, sleepiness, disordered sleep, restlessness, aggression, impaired concentration, reduced alertness and reaction time, depression, confusion, speech and visual disorders, slurred speech, shakiness, partial paralysis, sensory disturbances, dizziness, helplessness.
The following signs may also occur:
sweating, clammy skin, anxiety, accelerated heartbeat, high blood pressure, palpitations, 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 convulsions, 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.

Children and adolescents
Glimepiride Tablets is not recommended for use in children under 18 years of age.

Other medicines and Glimepiride tablets:
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

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

The following medicines can increase the blood sugar lowering effect of Glimepiride tablets. This can lead to a risk of hypoglycaemia (low blood sugar):
- Medicines to treat pain and inflammation (phenylbutazone, azopropazone, oxyphenbutazone, aspirin-like medicines)
- Other medicines to treat diabetes mellitus (such as insulin or metformin)
- Medicines supporting muscle build up (anabolics)
- Medicines to inhibit blood clotting (coumarin derivatives such as warfarin)
- Medicines used to reduce weight (fenfluramine)
- Medicines called anti-arrhythmic agents used to control abnormal heart beat (disopyramide)
- Medicines lowering high cholesterol level (fibrates)
- Medicines lowering high blood pressure (ACE inhibitors)
- Medicines to treat depression (fluoxetine, MAO inhibitors)
- Medicines to treat gout (allopurinol, probenecid, sulfinpyrazone)
- Medicines to treat cancer (cyclophosphamide, ifosfamide, trofosfamide)
- Medicines to treat bacterial and fungal infections (tetracyclines, chloramphenicol, fluconazole, miconazole, quinolones, clarithromycin)
- Medicines to treat nasal allergies such as hay fever (tritoqualine)
- Medicines to increase circulation when given in a high dose intravenous infusion (pentoxifylline)
- Medicines to treat urinary infections (such as some long acting sulfonamides)
- Medicines used for male sex hormone replacement therapy
- Medicines called sympatholytics to treat high blood pressure, heart failure, or prostate symptoms

The following medicines may decrease the blood sugar lowering effect of Glimepiride Tablets. This can lead to a risk of hyperglycaemia (high blood sugar level):
- Medicines containing female sex hormones (oestrogens, progestogens)
- Medicines supporting urine production (thiazide diuretics)
- 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 seizures (phenytoin)
- Medicines to treat high blood pressure or lowering blood sugar (diazoxide)
- Medicines to treat severe low blood sugar levels (glucagon)
- Medicines to treat nervousness and sleep problems (barbiturates)
- Medicines to treat infections, tuberculosis (rifampicin)
- Medicines to treat increased pressure in the eye (azetazolamide)

The following medicines can increase or decrease the blood sugar lowering effect of Glimepiride Tablets:
- 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.
- Medicines to treat stomach ulcers (called H_2 antagonists)

Glimepiride tablets 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 Tablets. To avoid this effect, you should be advised to take Glimepiride Tablets at least 4 hours before colesevelam.

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

Pregnancy and breast-feeding:
Pregnancy
Glimepiride Tablets 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
Glimepiride may pass into breast milk. Glimepiride should not be taken during breast feeding.
Ask your doctor or pharmacist for advice before taking this medicine.
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

Glimepiride Tablets contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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

Taking this medicine
- 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 medicine on schedule as prescribed by your doctor. It is important not to leave out any meal when you are on Glimepiride Tablets
- Swallow the tablets whole with at least half glass of water. Do not crush or chew the tablets
- Each tablet can be divided into equal doses

How much to take
The dose of Glimepiride Tablets depends on your needs, condition and results of blood and urine sugar tests and is

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determined by your doctor. Do not take more tablets than your doctor has prescribed.
- The usual starting dose is one Glimepiride 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 Glimepiride tablet per day.
- A combination therapy of glimepiride plus metformin or of glimepiride plus insulin may be initiated. In such a case your doctor will determine the proper doses of glimepiride, metformin or insulin individually for you
- If your weight, changes or if you change your lifestyle, or you are in a stress situation this may require changed Glimepiride Tablets doses, therefore inform your doctor.
- If you feel the effect of your medicine is too weak or too strong do not change the dose yourself, but ask your doctor

If you take more Glimepiride Tablets than you should
If you happen to have taken too much Glimepiride Tablets or an additional dose there is a danger of hypoglycaemia (signs of hypoglycaemia see section 2) 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. 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. 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 severe neurological failure are cases of medical emergency requiring immediate medical treatment and admission into hospital. It should be ensured that there is always a pre-informed person that can call a doctor in case of emergency.

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

If you stop taking Glimepiride Tablets
If you interrupt or stop the treatment you should be aware that the desired blood sugar lowering effect is not achieved or that the disease will deteriorate again. Keep taking Glimepiride Tablets until your doctor tells you to stop.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine 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 while taking Glimepiride Tablets:
Rare side effects (may affect up to 1 in 1000 people)
- Lower blood sugar than normal (hypoglycaemia) (see section 2)
- 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
Glimepiride tablets
- Weight gain
- Hair loss
- Changes in your sense of taste

Very rare side effects (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**.
- Abnormal liver function including yellowing of the skin and eyes (jaundice), impairment of 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)
- 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 medicine may occur
- Problems with your sight may occur when beginning treatment with Glimepiride Tablets. This is due to changes in blood sugar levels and should soon improve
- Increased liver enzymes
- Severe unusual bleeding or bruising under the skin

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 Yellow Card 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
- This medicinal product does not require any special temperature storage condition. Store in the original package in order to protect from moisture. Keep the blister in the outer carton.
- Do not use this medicine after the expiry date which is stated on the carton (EXP). The expiry date refers to the last day of that month.
- Do not use this medicine if you notice visible signs of deterioration.
- 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 contains:
The active substance is Glimepiride.
For 1 mg: Each tablet contains 1 mg of glimepiride.
For 2 mg: Each tablet contains 2 mg of glimepiride.
For 3 mg: Each tablet contains 3 mg of glimepiride.
For 4 mg: Each tablet contains 4 mg of glimepiride.

The other ingredients are:
Core tablet: lactose monohydrate, sodium starch glycolate (type A), povidone (K-30), magnesium stearate

Coloring agent:
Glimepiride Tablets 1 mg: Iron oxide red (E172)
Glimepiride Tablets 2 mg: Iron oxide red (E172)
Glimepiride Tablets 3 mg: Iron oxide yellow (E172)

What Glimepiride Tablets looks like and contents of the pack

Glimepiride Tablets 1 mg: Pink coloured round, flat uncoated tablets with beveled edges and score line on one side and plain on other side.
Glimepiride Tablets 2 mg: Light pink coloured oval shaped, uncoated tablets with score line on one side and plain on other side.
Glimepiride Tablets 3 mg: Pale yellow, oval shaped uncoated tablets with score line on one side and plain on other side.
Glimepiride Tablets 4 mg: White oval shaped uncoated tablets with score line on one side and plain on other side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses

Glimepiride Tablets are available in blister pack of 10, 30, 60, 90, 120 and 180 tablets.

Not all pack sizes may be marketed.

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This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Name of the member state	Name of the medicinal product
Estonia	Glimepiride Accord 1mg/2mg/ 3mg/ 4mg tabletid
France	Glimepiride Accord Healthcare 1 mg/ 2 mg/ 3 mg/ 4 mg Comprimes
Germany	Glimepiride Accord 1 mg/ 2 mg/ 3 mg/ 4 mg Tabletten
Ireland	Glimepiride 1 mg/ 2 mg/ 3 mg/ 4 mg Tablets
Italy	Glimepiride Accord Healthcare 2 mg/ 3 mg/ 4 mg Compresse
Latvia	Glimepiride Accord 1 mg/ 2 mg/ 3 mg/ 4 mg Tabletes
Lithuania	Glimepiride Accord 1 mg/ 2 mg/ 3 mg/ 4 mg tablets
The Netherlands	Glimepiride Accord 1 mg/ 2 mg/ 3 mg/ 4 mg Tabletten
Poland	Glimepiride Accord
Portugal	Glimepirida Accord 1 mg/ 2 mg/ 3 mg/ 4 mg Comprimidos
United Kingdom (Northern Ireland)	Glimepiride 1 mg/ 2 mg/ 3 mg/ 4 mg Tablets

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