

Gliclazide 40mg Tablets

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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1 What Gliclazide tablets are and what they are used for

Gliclazide belongs to a group of medicines called sulfonylureas that are used to lower the blood sugar level.

Gliclazide tablets are used in the treatment of diabetes mellitus when diet, physical exercise and weight loss alone fails to lower blood glucose (sugar). They are not for use in children or in patients with diabetes requiring insulin.

2 What you need to know before you take Gliclazide tablets

Do not take Gliclazide tablets and tell your doctor if you:

- are **allergic** to gliclazide or any of the other ingredients of this medicine (listed in section

6), to other medicines of the same group (sulfonylureas), to other related medicines (hypoglycaemic sulfonamides)

- have **insulin-dependent diabetes** (type 1)
- have ketone bodies and sugar in your urine (this may mean you have **keto-acidosis**), a **diabetic pre-coma** and **coma**
- have severe **kidney** or **liver** disease
- are taking **miconazole** (a treatment for fungal infections. See Other medicines and Gliclazide tablets)
- are **breast-feeding** (see Pregnancy and breast-feeding).

Warnings and precautions

Talk to your doctor or pharmacist before taking Gliclazide tablets. You should observe the treatment plan prescribed by your doctor to achieve proper blood sugar levels. This means, apart from regular tablet intake, you observe the dietary regime, have physical exercise and where necessary, reduce weight.

During gliclazide treatment, regular monitoring of your blood (and possibly urine) sugar level and also your glycated haemoglobin (HbA1c) is necessary.

In the first few weeks of treatment the risk of having reduced blood sugar levels (hypoglycaemia) may be increased. So particularly close medical monitoring is necessary.

Low blood sugar may occur:

- if you have meals irregularly, skip meals altogether or are fasting
- if you are malnourished
- if you change your diet
- if you increase your physical activity and carbohydrate intake does not match this increase
- if you drink alcohol, especially in combination with skipped meals
- if you take other medicines or natural remedies at the same time
- if you take too high doses of gliclazide
- if you suffer from particular hormone-induced disorders (functional disorders of the thyroid gland, of the pituitary gland or adrenal cortex)

- if your kidney function or liver function is severely decreased.

If you have low blood sugar you may have the following symptoms: headache, intense hunger, nausea, vomiting, weariness, sleep disorders, restlessness, aggressiveness, poor concentration, reduced alertness and reaction time, depression, confusion, speech or visual disorders, tremor, sensory disturbances, dizziness and helplessness.

The following signs and symptoms may also occur: sweating, clammy skin, anxiety, fast or irregular heartbeat, high blood pressure, sudden strong pain in the chest that may radiate into nearby areas (angina pectoris).

If blood sugar levels continue to drop you may suffer from considerable confusion (delirium), develop convulsions, lose self control, your breathing may be shallow and your heartbeat slowed down, you may become unconscious.

In most cases the symptoms of low blood sugar vanish very quickly when you consume some form of sugar, e.g. glucose tablets, sugar cubes, sweet juice, sweetened tea. You should therefore always carry some form of sugar with you (glucose tablets, sugar cubes). Remember that artificial sweeteners are not effective.

Please contact your doctor or the nearest hospital if taking sugar does not help or if the symptoms recur.

Symptoms of low blood sugar may be absent, less obvious or develop very slowly or you are not aware in time that your blood sugar level has dropped. This may happen if you are an elderly patient taking certain medicines (e.g. those acting on the central nervous system and beta blockers).

If you are in stressful situations (e.g. accidents, surgical operations, fever etc.) your doctor may temporarily switch you to insulin therapy.

Symptoms of high blood sugar (hyperglycaemia) may occur when gliclazide has not yet sufficiently reduced the blood sugar, when you have not complied with the treatment plan prescribed by your doctor or in especially stressful situations. These may include thirst, frequent urination, dry mouth, dry itchy skin, skin infections and reduced performance.

- While taking Gliclazide tablets you should:
 - follow a regular diet: it is important to eat regular meals, including breakfast and never to miss or delay a meal
 - take your medicine regularly (see section 3 'How to take Gliclazide tablets')
 - check your blood glucose regularly as recommended by your doctor.

If you have a family history of or know you have the hereditary condition glucose-6-phosphate dehydrogenase (G6PD) deficiency (abnormality of red blood cells), contact your doctor before taking this medicinal product.

Cases of acute porphyria have been described with some other sulfonylurea drugs, in patients who have porphyria (inherited genetic disorders with accumulation in the body of porphyrins or porphyrin precursors).

Other medicines and Gliclazide tablets

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

The blood sugar lowering effect of gliclazide may be strengthened and signs of low blood sugar levels may occur when one of the following medicines is taken:

- other medicines used to treat high blood sugar (oral antidiabetics, GLP-1 receptor inhibitors or insulin)
- antibiotics (e.g. sulfonamides, clarithromycin)
- medicines to treat high blood pressure or heart failure (beta blockers, ACE-inhibitors such as captopril or enalapril)
- medicines to treat fungal infections (miconazole, fluconazole)
- medicines to treat ulcers in the stomach or duodenum (H2 receptor antagonists)
- medicines to treat depression (monoamine oxidase inhibitors)
- painkiller or antirheumatics (phenylbutazone, ibuprofen)
- medicines containing alcohol
- St John's Wort (*Hypericum perforatum*) preparations.

Blood glucose disturbance (low blood sugar and high blood sugar) can occur when a medicine belonging to a class of antibiotics called fluoroquinolones is taken at the same time as Gliclazide tablets, especially in elderly patients.

The blood glucose lowering effect of gliclazide may be weakened and raised blood sugar levels may occur when one of the following medicines is taken:

- medicines to treat disorders of the central nervous system (chlorpromazine)

- medicines to reduce inflammation (corticosteroids)
- medicines to treat asthma or used during labour (intravenous salbutamol, ritodrine and terbutaline)
- medicines to treat breast disorders, heavy menstrual bleeding and endometriosis (danazol).

Gliclazide tablets may increase the effects of medicines which reduce blood clotting (e.g. warfarin).

Consult your doctor before you start taking another medicinal product. If you go into hospital, tell the medical staff you are taking Gliclazide tablets.

Gliclazide tablets with food, drink and alcohol

Gliclazide can be taken with food and non-alcoholic drinks. Drinking alcohol is not recommended as it can alter the control of your diabetes.

Pregnancy and breast-feeding

Gliclazide tablets are not recommended for use during pregnancy. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. You must not take Gliclazide tablets while you are breast-feeding.

Driving and using machines

Provided your blood glucose levels are satisfactorily controlled on Gliclazide tablets, your ability to drive or use machines should not be affected. However, if your blood glucose levels become too low, this could adversely affect your concentration, and therefore your ability to perform these tasks.

Ask your doctor whether you can drive a car if you:

- have frequent episodes of low blood sugar
- have few or no warning signals of low blood sugar.

3 How to take Gliclazide 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.

These tablets should be taken with a glass of water before meals.

Recommended doses: Adults and the elderly

The starting dose is usually 40-80mg once daily and may be increased to a total daily dose of 320mg.

Do not take more than the maximum of 160mg as single dose. For doses of 320mg this will be split over the day.

If a combination therapy of Gliclazide tablets with metformin, an alpha glucosidase inhibitor, a thiazolidinedione, a dipeptidyl peptidase-4 inhibitor, a GLP-1 receptor agonist or insulin is initiated, your doctor will determine the proper dose of each medicine individually for you. If you notice that your blood sugar levels are high although you are taking the medicine as prescribed, you should contact your doctor or pharmacist.

Use in children
Not recommended.

If you take more Gliclazide tablets than you should

If you take too many tablets, contact your doctor or the nearest hospital Accident & Emergency department immediately. The signs of overdose are those of low blood sugar described in Section 2. The symptoms can be helped by taking sugar (4 to 6 lumps) or sugary drinks straight away, followed by a substantial snack or meal. If the patient is unconscious, immediately inform a doctor and call the emergency services.

If you forget to take Gliclazide tablets

Take it as soon as you remember, unless it is nearly time for your next dose. Then carry on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Gliclazide tablets

As the treatment for diabetes is usually life long, you should discuss with your doctor before stopping this medicinal product. Stopping could cause high blood sugar (hyperglycaemia) which increases the risk of developing complications of diabetes.

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 can cause side effects although not everybody gets them.

Low blood sugar

The most commonly observed side effect is low blood sugar. For symptoms and signs see section Warnings and Precautions. If left untreated, these symptoms could progress to drowsiness, loss of consciousness or possibly coma. If an episode of low blood sugar is severe

or prolonged, even if it is temporarily controlled by eating sugar, you should seek immediate medical attention.

Other side effects

- **Digestive disorders:** Abdominal pain, nausea, vomiting, indigestion, diarrhoea and constipation. These effects are reduced when Gliclazide tablets are taken with a meal as recommended.
- **Skin disorders:** Skin reactions such as rash, redness, itching, hives, blisters, angioedema (rapid swelling of tissues such as eyelids, face, lips, mouth, tongue or throat that may result in breathing difficulty) have been reported. The rash may progress to widespread blistering or peeling of the skin. Exceptionally, signs of severe hypersensitivity reactions (DRESS) have been reported: initially as flu-like symptoms and a rash on the face then an extended rash with a high temperature.
- **Blood disorders:** Decrease in the number of cells in the blood (e.g. platelets, red and white blood cells) which may cause paleness, prolonged bleeding, bruising, sore throat and fever. These symptoms usually stop when the treatment is discontinued.
- **Liver disorders:** There have been isolated reports of abnormal liver function which can cause yellow skin and eyes. If you get this, see your doctor immediately. The symptoms generally disappear if the drug is stopped. Your doctor will decide whether to stop your treatment.
- **Eye disorders:** Your vision may be affected for a short time, especially at the start of treatment. This effect is due to changes in blood sugar levels.

As for other sulfonylureas, the following adverse events have been observed: cases of severe changes in the number of blood cells and allergic inflammation of the wall of blood vessels, reduction in blood sodium (hyponatraemia), symptoms of liver impairment (e.g. jaundice) which in most cases disappeared after withdrawal of the sulfonylurea, but may lead to life threatening liver failure in isolated cases.

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 Gliclazide tablets

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions. Do not use this medicine after the expiry date stated on the carton. 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 Gliclazide tablets contain

- The active substance is gliclazide. Each tablet contains 40mg of gliclazide.
- The other ingredients are microcrystalline cellulose, pregelatinised starch, maize starch, stearic acid, magnesium stearate.

What Gliclazide tablets look like and contents of the pack

Gliclazide tablets are white, circular, flat, bevelled-edge uncoated tablet plain on one face and the identifying letters "GU" on the reverse.

Pack size 28.

Marketing Authorisation Holder

Accord Healthcare Limited
Sage House
319 Pinner Road
North Harrow
Middlesex
HA1 4HF
United Kingdom

Manufacturer

Accord, Barnstaple, EX32 8NS, UK

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