

Gliclazide 80mg 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 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.

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1 What Gliclazide tablets are and what they are used for

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

Gliclazide tablets are used to treat maturity onset diabetes in patients that is not controlled by diet alone.

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 ingredients of this medicine (listed in section 6), to other medicines of the same group (sulfonylureas) or other related medicines (hypoglycaemic sulfonylamides). An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue
- are **breast feeding**
- have **severe liver or kidney** disease
- have **porphyria** (a hereditary disease affecting the liver or bone marrow)
- have ever had a severe **diabetic reaction** (such as "acidosis" or diabetic coma).
- have **Type I diabetes**
- are diabetic and need an **operation**, suffered a **severe trauma** or **infection**
- take **miconazole** (for fungal infections).

Warnings and precautions

Talk to your doctor or pharmacist before taking Gliclazide tablets if you:

- have **liver or kidney** problems

- have an inherited condition where your red blood cells don't produce enough of the enzyme **G6PD** (glucose 6 phosphate dehydrogenase)
- suffer from particular **hormone-induced disorders** (functional disorders of the thyroid gland, of the pituitary gland or adrenal cortex)
- are at risk of developing **low blood sugar** (hypoglycaemia)
 - take meals irregularly or skip meals altogether, are fasting, malnourished, change your diet, increase your physical activity and carbohydrate intake does not match this increase, drink alcohol, especially in combination with skipped meals
- take other medicines or **natural remedies** at the same time
- take **too high doses** of gliclazide.

You should observe the treatment plan prescribed by your doctor to achieve proper blood sugar levels. This means, apart from regular tablet intake, to observe the dietary regimen, 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.

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, including medicines obtained without a prescription.

Especially:

- other medicines used to treat high blood sugar (oral antidiabetic, GLP-1 receptor inhibitors or insulin)
- antibiotics (sulfonamides, clarithromycin)
- medicines to treat high blood pressure such as beta blockers (e.g. propranolol, atenolol), ACE inhibitors (e.g. captopril), Angiotensin-II antagonists (e.g. losartan), nifedipine, diazoxide
- medicines used to treat infections such as co-trimoxazole, fluconazole, rifampicin, chloramphenicol, oral forms of miconazole (see section 2), sulfonamides such as sulfafurazole or tetracycline compounds (e.g. tetracycline)
- medicines used to prevent blood clotting (e.g. warfarin)
- medicines used to treat depression such as monoamine oxidase inhibitors (MAOIs e.g. moclobemide)
- medicines used to treat mental health problems such as lithium, phenothiazine derivatives (e.g. chlorpromazine)
- corticosteroids (e.g. prednisolone), glucocorticoids and tetracosactrin used to reduce inflammation in the body
- phenylbutazone, azapropazone and other NSAIDs (non-steroidal anti-inflammatory drugs)
- diuretics (water tablets) such as bendroflumethiazide, hydrochlorothiazide, furosemide
- oral contraceptives (the "pill")
- salicylates (e.g. aspirin used for muscular or skeletal disorders)
- sulfinpyrazone (used for gout)
- aminoglutethimide (used to treat breast or prostate cancer)
- hormones such as testosterone, octreotide or thyroid hormones (e.g. thyroxine)
- cimetidine (used to treat stomach ulcers)
- clofibrate (used to treat high cholesterol in the blood)
- disopyramide (for irregular heartbeats)
- laxatives
- other medicines used to treat high blood sugar
- medicines containing alcohol

- chlorpromazine to treat disorders of the central nervous system
- medicines to treat asthma or used during labour (intravenous salbutamol, ritodrine and terbutaline)
- danazol to treat breast disorders, heavy menstrual bleeding and endometriosis
- 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.

Gliclazide tablets with alcohol

Patients should not consume alcohol in combination with Gliclazide tablets.

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 breastfeeding.

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 (hypoglycaemia),
- 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. The tablet can be cut in half.

Recommended dose:

Adults and the elderly

The starting dose is usually 40-80mg once daily and may be increased to a total daily dose of 40-320mg. Do not take more than the maximum of 160mg as single dose, for doses of 320mg this will be split over the day

Use in children

Not recommended.

If you take more Gliclazide tablets than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, **contact your nearest hospital casualty department or tell your doctor immediately.** Signs of an overdose include symptoms of low blood sugar such as sweating, trembling, weakness, double vision, palpitations, confusion.

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

Talk to your doctor before you stop taking the tablets and follow their advice.

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

4 Possible side effects

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

Stop taking this medicine and see your doctor immediately if you experience any of the following side effects that can be serious:

- An allergic reaction (skin rash, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing).

- Angioedema (rapid swelling of tissues such as eyelids, face, lips, mouth, tongue or throat that may result in breathing difficulty).
- Signs of severe hypersensitivity reactions (DRESS) (initially as flu-like symptoms and a rash on the face then an extended rash with a high temperature).
- A rash progressing to widespread blistering or peeling of the skin.
- Symptoms of low blood sugar level (hypoglycaemia) (sweating, clammy skin, trembling, weakness, double vision, palpitations, confusion, headache, hunger, feeling or being sick, sleep disorders, feeling agitated, unable to concentrate, drowsiness, loss of consciousness, slowed reactions, depression, trouble seeing or speaking, paralysis, numbness, dizziness, loss of self-control, sensing or seeing things that are not there, difficulty breathing, slowed or faster heartbeat, chest pains (anginal)).
- Hepatitis or liver failure causing fatigue, weakness, loss of appetite, weight loss, fever, changes in liver enzymes (seen in tests), jaundice (yellowing of the skin or whites of the eyes).

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

Gastrointestinal - feeling or being sick, abdominal pain or discomfort, indigestion, diarrhoea, constipation.

Skin - skin rashes or pale skin, redness, itching and hives.

Blood - gliclazide may affect the cells in your blood, which can cause anaemia or mean that you are more likely to catch infections or have a fever or sore throat, or develop bruising or bleeding.

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.

Other - general feeling of being unwell, reduction in blood sodium (hyponatraemia).

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 at: 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 out of the sight and reach of children.

Store below 25°C in a dry place.

Do not take 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 dispose of medicines 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 80mg of gliclazide.
- The other ingredients are maize starch, stearic acid, magnesium stearate, microcrystalline cellulose (E460).

What Gliclazide tablets look like and size of the pack

Gliclazide tablets are white, circular, flat, bevelled-edge coated tablets plain with a central division line on one face and the identifying letters "G" and "Z" on either side of a central division line on the reverse.

Pack sizes are 28 and 60.

Marketing Authorisation Holder and Manufacturer

Accord, Barnstaple, EX32 8NS, UK

This leaflet was last revised in March 2021