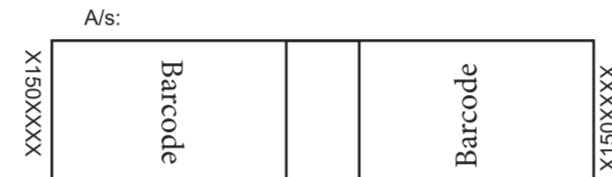


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PACKAGE LEAFLET: INFORMATION FOR THE USER
Gliclazide 80mg Tablets
gliclazide

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 Gliclazide Tablets are and what they are used for
2. What you need to know before you take Gliclazide Tablets
3. How to take Gliclazide Tablets
4. Possible side effects
5. How to store Gliclazide Tablets
6. Contents of the pack and other information

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

Gliclazide belongs to a group of medicines called 'sulphonylureas'. It is an oral hypoglycaemic medicine (blood sugar lowering drug). Gliclazide Tablet is used to keep blood sugar at the correct level in adults with non-insulin dependent diabetes when it is not controlled by diet, physical exercise and weight loss alone.

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

Do NOT take Gliclazide Tablets:

- if you are allergic to Gliclazide or any of the other ingredients of Gliclazide tablets (listed in section 6), to other medicines of the same group (sulphonylureas), to other related medicines (hypoglycaemic sulfonamides),
- if you have insulin-dependent diabetes (Type I)
- if you have severe liver or kidney disease,
- if you have ketone bodies and sugar in your urine (this may mean you have keto-acidosis), a diabetic pre-coma or coma,
- if you are breast-feeding (see Section **Pregnancy and breast-feeding**).
- if you are taking miconazole (a treatment for fungal infections) or antibiotics (quinolones) (see section **Other medicines and Gliclazide Tablets**)

Warnings and precautions

Talk to your doctor or pharmacist before taking Gliclazide Tablets. Follow your doctor's advice about diet and treatment. This is to reduce the chances of very low blood sugar (hypoglycaemia). Make sure your doctor knows:

- if you have an operation, a serious injury, fever or infection,
- difficulty in eating,
- if you plan a pregnancy or become pregnant,
- if you are taking any of the medicines listed in other medicines and Gliclazide Tablets.
- Tell your dentist about your treatment.

Dietary advice

This medicine may cause episodes of low blood sugar (hypoglycaemia). This is more likely if:

- you are on strict diet,
- your diet is poorly balanced,
- you are taking prolonged or strenuous exercise,
- you are taking several medicines for high blood sugar (see **Other medicines and Gliclazide tablets**).

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 heart beat 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, for instance 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.

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 **How to take Gliclazide Tablets**),
- check your blood glucose regularly as recommended by your doctor.

Blood glucose disturbance (low blood sugar and high blood sugar) can occur when gliclazide is prescribed at the same time as medicines belonging to a class of antibiotics called fluoroquinolones, especially in elderly patients. In this case, your doctor will remind you the importance of monitoring your blood glucose.

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 sulphonylurea drugs, in patients who have porphyria (inherited genetic disorders with accumulation in the body of porphyrins or porphyrin precursors).

Children and adolescents

Gliclazide Tablets is not recommended for use in children.

Other medicines and Gliclazide Tablets

Tell your doctor or pharmacist if you are taking or 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. sulphonamides, clarithromycin, quinolones),
- 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

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 reducing inflammation (corticosteroids),
- medicines to treat breast disorders and heavy menstrual bleeding and endometriosis (danazol)
- medicines to treat asthma or used during labour (intravenous salbutamol, ritodrine and terbutaline),
- St John's Wort - *Hypericum perforatum*-preparations to treat mild to moderate depressive episodes.

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 Tablets 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 Tablet is not recommended for use during pregnancy. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist 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 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 (hypoglycaemia).

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Gliclazide tablets contains Lactose -

Lactose is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

3. How to take Gliclazide Tablets

Dose

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Gliclazide Tablets are for oral use. Take your tablet(s) with a glass of water (and preferably at the same time each day). Swallow your tablets whole. Do not chew them. You must always eat a meal after taking your tablet(s).

The recommended dose is as follows:

Adults and Elderly: The usual starting dose is 40 to 80mg (½ or 1 tablet) daily, adjusted according to your response, up to a maximum of 320mg (four tablets) daily. Up to 160mg (two tablets) can be taken at one time.

Your starting dose will be reduced if you are elderly or have liver or kidney problems.

Use in children: Gliclazide is not recommended for use in children.

If a combination therapy of Gliclazide Tablet 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.

If you take more Gliclazide Tablets than you should

If you or someone else accidentally takes more Gliclazide Tablets than you should, seek **immediate** medical help by contacting your doctor or nearest hospital casualty department. Take the carton and any remaining tablets you have with you. The signs of overdose are those of low blood sugar (hypoglycaemia) 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

It is important to take your medicine everyday as regular treatment works better. If you have missed a dose, take it as soon as you remember unless it is nearly time for your next dose. Do NOT take a double dose to make up for a forgotten one.

If you stop taking Gliclazide Tablets

As the treatment of diabetes is 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 or pharmacist.

4. Possible side effects

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

Low blood sugar (Hypoglycaemia)

The most commonly observed side effect is low blood sugar (hypoglycaemia). 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 80mg 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. Rash may progress to widespread blistering or peeling of the skin. If you develop this, stop taking Gliclazide Tablets, seek urgent advice from a doctor and tell him that you are taking this medicine. 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 sulphonylureas, 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 sulphonylurea, 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 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 this medicine out of the sight and reach of children.

Do not use your medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 25°C.

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 to protect the environment.

6. Contents of the pack and other information

What Gliclazide tablet contains

The active substance is gliclazide. Each tablet contains 80mg of gliclazide.

The other ingredients are: lactose monohydrate, silicon dioxide, pregelatinised maize starch, talc and magnesium stearate.

What Gliclazide Tablets look like and the contents of the pack

Gliclazide tablets 80mg are white, round tablets scored on one side with G on the other side 80

The registered pack sizes are 28 and 60 tablets.

Marketing Authorisation Holder:

Milpharm Limited,
Ares, Odyssey Business Park,
West End Road,
South Ruislip, HA4 6QD
United Kingdom

Manufacturer:

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