



PACKAGE LEAFLET: INFORMATION FOR THE USER

Gliclazide 80 mg 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 of the 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 is one of a group of medicines called sulfonylureas. It is an oral hypoglycaemic medicine (blood sugar lowering drug). Gliclazide 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 this medicine (listed in section 6), to other medicines of the same group (sulfonylureas), to other related medicines (hypoglycaemic sulfonamides),
- if you have insulin-dependent diabetes (type 1),
- 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 have severe kidney or liver disease,
- if you are taking miconazole (a treatment for fungal infections) (see Taking other medicines),
- if you are breast-feeding (see Pregnancy and breast-feeding).

Gliclazide is not recommended for use in children.

If you have been told by your doctor that you have an intolerance to some sugars (e.g. glucose, lactose, galactose), contact your doctor before taking this medicinal product.

Warnings and precautions

Talk to your doctor or pharmacist before taking Gliclazide

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 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;

Low blood sugar (hypoglycaemia) may occur if you:

- take meals irregularly or skip meals altogether, if you are fasting,
- are 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,
- suffer from particular hormone-induced disorders (Functional disorders of the thyroid gland, of the pituitary gland or adrenal cortex),
- 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 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, 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.

Symptom 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 (those acting on the central nervous system and β -blockers).

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 special stress situations. These may include thirst, frequent urination, dry mouth, dry itchy skin, skin infections and reduced performance.

If these symptoms occurred you must contact your doctor or pharmacist.

While taking this medicine 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.

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.

Other medicines and Gliclazide Tablets:

Tell your doctor or pharmacist if you are taking, have recently taken any other medicines, including medicines obtained without a prescription, as they may interact with your tablet.

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

Gliclazide 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.

Taking 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 in an unpredictable manner.

Pregnancy and breast-feeding

Do not take this medicine if you are pregnant, thinking of becoming pregnant or breast-feeding. Tell your doctor if you are taking Gliclazide tablets and are breastfeeding or planning to breast-feed your baby.

Driving and using machines

Provided your blood glucose levels are satisfactorily controlled on this medicine, 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 (hypoglycaemia).

3. How to take Gliclazide Tablets

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

Change in external factors (e.g. weight reduction, change in life style, stress) or improvements in the blood sugar control may require changed gliclazide doses.

Gliclazide Tablets should be taken orally with food, either with breakfast or the first main meal of the day. The usual dosage 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.

If a combination therapy of Gliclazide 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.

Children: Gliclazide is not recommended for use in children.

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 (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

If you forget to take a dose, do not worry, just wait until it is time for your next dose. Do not take a double dose to make up for a forgotten tablet.

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 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 is taken with a meal as recommended.

Skin disorders: Skin reactions such as rash, redness, itching, hives, 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 or 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. 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 sight and reach of children.

Do not use your medicine after the expiry date stated on the label. The expiry date refers to the last day of that month. Do not store above 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist to dispose of medicines no longer required. These measures will help to 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: lactose monohydrate, silicon dioxide, pregelatinised maize starch, talc and magnesium stearate.

What Gliclazide Tablets looks like and contents of the pack

Gliclazide 80mg tablets are white, round tablets scored on one side with G80 on the other side.

The registered pack sizes are 28 and 60 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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