

Gliclazide 80 mg Tablets (Gliclazide)

Package leaflet: Information for the user

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

What is in this leaflet

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1 What Gliclazide is and what it is used for

Gliclazide belongs to a group of drugs called hypoglycaemic sulphonylureas. Sulphonylureas act by stimulating the release of insulin from the pancreas and so lower the amount of sugar in your blood.

Gliclazide is used to treat diabetes mellitus in adults.

2 What you need to know before you take Gliclazide

Do not take Gliclazide:

- if you are allergic (hypersensitive) to gliclazide or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to sulphonylureas or related drugs (hypoglycaemic sulphonamides)
- if you have severe liver or kidney problems
- if you are breast feeding
- if you have juvenile-onset or insulin-dependent diabetes (Type 1)
- if you have diabetic ketoacidosis (presence of ketones in the urine)
- if you are treated with miconazole (an antifungal medicine).

These tablets should not be used in patients suffering from a diabetic coma or pre-coma.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Gliclazide:

- if you suffer from liver or kidney problems
- if you suffer from acute porphyria (an enzyme deficiency)
- if you have operation, a serious injury, fever or infection, difficulty in eating
- if you plan a pregnancy or become pregnant
- if you have an inherited condition where your red blood cells don't produce enough of the enzyme G6PD (glucose 6 phosphate dehydrogenase)

Follow your doctor's advice about diet and your treatment in order to reduce the chances of very low blood sugar levels (hypoglycaemia) occurring.

Dietary advice

Gliclazide may cause episodes of low blood sugar (Hypoglycaemia).

Hypoglycaemia is more likely to happen in the following situations:

- if you are on a strict diet
- if you eat a poorly balanced diet
- when you take prolonged or strenuous exercise
- when you drink alcohol
- if you are taking several medicines to lower your blood sugar levels
- if you have thyroid problems, or underactive pituitary or adrenal glands.

If you have low blood sugar level you may have the following symptoms: sweating, intense hunger, shaking, irregular or fast heart beat, problems with your vision or feeling unwell, you must immediately eat some sugar or food containing sugar, or have a sugary drink. Remember that artificial sweeteners are not effective.

While you are taking Gliclazide you should:

- follow a regular diet as it is important to eat meals regularly and not to miss or delay a meal
- take your medicine regularly
- check your blood glucose on a regular basis, as recommended by your doctor.

Other medicines and Gliclazide

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

You should not take Gliclazide with miconazole (an anti-fungal medicine used for the treatment and prevention of oral and stomach fungal infections).

Talk to your doctor if you are taking any of the following:

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:

- phenylbutazone, a non-steroidal anti-inflammatory drug (NSAID), used to treat ankylosing spondylitis
- medicines containing alcohol
- other medicines used to treat high blood sugar (e. g. insulin, acarbose, biguanides)
- salicylates, e.g. aspirin (non steroidal anti-inflammatory agent)
- angiotensin converting enzyme (ACE) inhibitors such as captopril, or enalapril (used to treat high blood pressure and heart failure)
- H₂ receptor antagonists for ulcers or dyspepsia
- monoamine-oxidase inhibitors (MAOIs), used for the treatment of depression
- beta-blockers, e.g. propranolol, used to treat high blood pressure
- fluconazole (an oral treatment for fungal infection)
- sulphonamides used to treat bacterial infections.

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:

- danazol (used to treat breast disorders, heavy menstrual bleeding and endometriosis)
- corticosteroids, used to treat conditions such as rheumatism and asthma, e.g. prednisolone
- phenothiazine derivatives, used to treat anxiety or mental illness, e.g. chlorpromazine
- intravenous ritodrine and terbutaline (used during labour)
- intravenous salbutamol (for asthma)
- anticoagulants, used to prevent blood clots, e.g. warfarin.

Your doctor may need to change your dose of Gliclazide if you are taking other medication.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Gliclazide is not recommended for use during pregnancy. If you are planning a pregnancy, or become pregnant, inform your doctor so that he may prescribe a more suitable treatment for you.

You must not take Gliclazide while you are breastfeeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

If you experience the symptoms of low blood sugar (hypoglycaemia) such as light-headedness, sweating and a fast heart beat you should not drive or operate

machinery. Low blood sugar may occur at the beginning of treatment while your doctor is trying to find the dose that best suits you. Your doctor will give you further advice. If affected do not drive or operate machinery.

Gliclazide contains lactose monohydrate

- Patients who are intolerant to **lactose** should note that Gliclazide tablets contain a small amount of lactose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3 How to take Gliclazide

Always take Gliclazide exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure

Gliclazide tablets should be taken before a meal. The tablets should be swallowed, preferably with a drink of water.

• Adults:

At first you may be prescribed half or one tablet (40 or 80 mg) a day. Your doctor may increase your dose if your blood sugar level does not lower to a suitable level, to a maximum 320 mg taken as two tablets twice daily.

• Older people:

No dosage adjustment is needed, however care should be taken due to the increased risk of low blood sugar if you are elderly.

• Use in Children:

Gliclazide is not recommended for use in children for the treatment of juvenile-onset diabetes.

If you take more Gliclazide than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause low blood sugar. If you feel faint, shaky, sweaty and your heart is pounding you should eat or drink something sugary. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Gliclazide

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose. Take the remaining doses at the correct time.

If you stop taking Gliclazide

Do not stop taking your medicine without talking to your doctor first even if you feel better.

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.

If the following happens, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

The most frequent side effects are due to low blood sugar (hypoglycaemia):

- light-headedness
- a pounding heart
- clamminess or sweaty palms.

These may mean your blood sugar is too low and the dose of Gliclazide is not right for you. If you think this is happening to you, you should eat or drink something sugary and then contact your doctor or pharmacist immediately.

The following side effects have also been reported:

- abdominal pain, indigestion, feeling sick, being sick, diarrhoea or constipation. These can be avoided if you take your medicine during a meal.
- rash, itching, redness, hives
- blood disorders which may cause unusual tiredness or weakness, fever or chills, ulcers in your mouth or throat, unusual bleeding or unexplained bruising. These symptoms usually stop when the treatment is discontinued
- liver failure, inflammation of the liver, yellowing of the skin and whites of the eyes (jaundice). The symptoms generally disappear if the drug is stopped. Your doctor will decide whether to stop your treatment.
- 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.

With this type of blood sugar lowering medicine (sulphonyl urea), cases of severe changes in the number of blood cells and allergic inflammation of the wall of blood vessels have been described. Symptoms of liver impairment (e.g. jaundice) have been observed which in most cases disappeared after withdrawal of the sulphonyl urea, 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 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 in the safety of this medicine.

5 How to store Gliclazide

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

Do not use Gliclazide after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month.

Do not store above 25°C. Do not transfer to another container.

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 ingredient is gliclazide.
- The other ingredients are lactose monohydrate, silicon dioxide (E551), pregelatinised maize starch, talc (E553b) and magnesium stearate (E572).

What Gliclazide tablets look like and contents of the pack:

- The Gliclazide 80 mg tablets are white, flat, round tablets marked with a double score on one side and '3G5' on the other side.
 - The product is available in pack sizes of 28 and 60 tablets.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder: Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer: TEVA Pharmaceutical Works Private Limited Company, Pallagi Street 13, Debrecen, HU-4042, Hungary

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