

**Package leaflet: Information for the user****GLICLAZIDE 80 MG 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.

**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 80 mg contains the active substance gliclazide, one of a group of medicines sulfonylureas. It is an oral hypoglycaemic medicine (blood sugar lowering drug).
- Gliclazide Tablets are used to keep blood sugar at the correct level in adults with non-insulin dependent diabetes (type 2) 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 these 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)
- have insulin-dependent diabetes (type 1)
- suffer from severe kidney or liver problems
- have ketone bodies and sugar in your urine (this may mean you have keto-acidosis)
- suffer from a diabetic pre-coma and coma.
- are taking miconazole (a treatment for fungal infections) or antibiotics (quinolones) (see section **Other medicines and Gliclazide Tablets**)
- are breast-feeding (see Pregnancy, breast-feeding and fertility)

Gliclazide Tablets are **not recommended** for use in children.

**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 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.

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 (hypoglycaemia) may occur if:

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

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 stress-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, if you take St John's Wort (*Hypericum perforatum*) preparations (See section '**Other medicines and Gliclazide Tablets**'), or in special stress situations. These may include thirst, frequent urination, dry mouth, dry itchy skin, skin infections and reduced performance.

If these symptoms occur, you must contact your doctor or pharmacist.

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 sulfonylurea drugs, in patients who have porphyria (inherited genetic disorder 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, 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 anti-rheumatics (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 asthma or used during labour (intravenous salbutamol, ritodrine and terbutaline),
- medicines to treat breast disorders, heavy menstrual bleeding and endometriosis (danazol).
- St John's Wort -*Hypericum perforatum*-preparations to treat mild to moderate depressive episodes.

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 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.

LXXX

140 mm

430 mm

**Taking Gliclazide 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, breast-feeding and fertility**

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 while taking this medicine, inform your doctor so that he may prescribe a more suitable treatment for you.

You must not take this medicine 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 (hypoglycaemia),
- have few or no warning signals of low blood sugar (hypoglycaemia).

**Gliclazide Tablets contain Lactose**

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

**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.

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

The recommended dose is one half to four tablets. This depends on the response to treatment. When the total daily dose exceeds two tablets, it should be divided into two equal doses taken morning and evening.

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).

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.

**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**

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of Gliclazide tablets, take the next dose at the usual time. 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 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.

**If you experience any of below mentioned side effects, stop taking the tablets and contact your doctor immediately. The symptoms generally disappear if the medicine is stopped. Your doctor will decide whether to stop your treatment.**

- 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.
- Decrease in the number of cells in the blood (for instance platelets, red and white blood cells) which may cause paleness, prolonged bleeding, bruising, sore throat and fever.
- There have been isolated reports of abnormal liver function which can cause yellow skin and eyes. If you get this, see your doctor immediately.

**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.

**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 (for instance 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 at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in 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 store above 25°C. Store in the original package.
- Do not use this medicine after the expiry date which is stated on the carton after EXP. 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 80mg of gliclazide.
- The other ingredients are Lactose monohydrate, microcrystalline cellulose, magnesium stearate, purified talc, croscarmellose sodium and povidone.

**What Gliclazide Tablets look like and contents of the pack**

- Gliclazide 80mg Tablets are white to off-white, circular, flat, bevelled edged, uncoated tablets with "80" on one side and a breakline on the reverse.
- These tablets are available in packs of 20, 28, 56, 60, 84, 100 tablets. Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Name and address: Bristol Laboratories Ltd,  
Unit 3, Canalside, Northbridge Road, Berkhamsted,  
Hertfordshire, HP4 1EG, United Kingdom

Telephone: 0044 (0)1442 200922  
Fax: 0044 (0)1442 873717  
Email: [info@bristol-labs.co.uk](mailto:info@bristol-labs.co.uk)

**Gliclazide 80mg Tablets; PL 17907/0068**

This leaflet was revised in September 2020.

To request a copy of this leaflet in Braille, large print or audio format, please contact the marketing authorisation holder at the address (or telephone, fax, email) above.