

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Gliclazide 80mg Tablets BP (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 a oral anti-diabetic drug belonging to a group of medicines called sulphonylureas . It acts by reducing the blood sugar levels in the body.

Gliclazide is used for the treatment of Type 2 (non-insulin dependent) diabetes mellitus particularly where diet and exercise changes alone have not been sufficient to control it. In type 2 diabetes, there is too much sugar (glucose) in your blood because your pancreas does not produce enough insulin or because it produces insulin that does not work properly.

#### **2. What you need to know before you take Gliclazide tablets**

##### **Do not take Gliclazide Tablets if :**

- you are allergic (hypersensitive) to gliclazide or any of the other ingredients of Gliclazide Tablets (see section 6).
- you are allergic to other medicines of the same group (sulphonylureas), or to other related medicines (hypoglycaemic sulphonamides).
- you are breastfeeding (see section “Pregnancy and breastfeeding”).
- you have insulin-dependent diabetes (type 1) you have ketone bodies and sugar in your urine (this means you have diabetic keto-acidosis), a diabetic pre-coma or coma.
- you are diabetic and undergoing surgery, after trauma or during serious infections
- you have severe kidney or liver disease.
- you take miconazole (for fungal infections).
- have porphyria (a hereditary disease affecting the liver or bone marrow).
- you have rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption

## **Children and adolescents**

Gliclazide tablets are not recommended for use in children.

If you think any of these situations applies to you, or if you have any questions or doubts about taking Gliclazide Tablets, then you should consult your doctor or pharmacist.

## **Warnings and precautions**

Talk to your doctor before taking Gliclazide 80mg. 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.

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
- if you are malnourished,
- if you change your diet,
- if you increase your physical activity and carbohydrate intake does not match this increase,
- if you drink alcohol, especially in combination with skipped meals,
- if you take other medicines or natural remedies at the same time,
- if you take too high doses of gliclazide,
- if you suffer from particular hormone-induced disorders (functional disorders of the thyroid gland, of the pituitary gland or adrenal cortex),
- if you 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, 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.

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 (for instance those acting on the central nervous system and beta blockers).

If you are in stress-situations (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 80mg"), 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 80mg 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 80mg),
- 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 disorders with accumulation in the body of porphyrins or porphyrin precursors).

### **Other medicines and Gliclazide tablets**

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

The treatment of your diabetes with Gliclazide Tablets may be affected by a number of other medicines you may have been prescribed or have bought from the chemist.

### **In particular, tell your doctor if you are taking any of the following:**

The following medicines may enhance the blood sugar lowering effect of this medicine and therefore increase the chance of low blood sugar (hypoglycaemia). If you start treatment with any of these your dose of Gliclazide Tablets may therefore need to be decreased:

- Medicines to treat high blood pressure or heart failure or irregular heartbeats (ACE inhibitors, Beta-blockers, Antiarrhythmics e.g. captopril, enalapril, propranolol, disopyramide).
- Medicines to treat ulcers in the stomach or duodenum (Antiulcers e.g. cimetidine).
- Medicines used to reduce high blood fat levels (Lipid lowering agents e.g. clofibrate).
- Medicines to treat depression (MAOI antidepressants, e.g. phenelzine).
- Medicines to treat fungal infections (Antifungals e.g. miconazole, fluconazole).
- Other medicines used to treat high blood sugar (Oral antidiabetics, GLP-1 receptor or insulin).
- Painkiller (including non steroidal anti-inflammatory drugs) or antirheumatics (e.g. phenylbutazone, azapropazone, ibuprofen, aspirin).
- Sulphonamide antibiotics, e.g. sulfamethoxazole, co-trimoxazole.
- Antibacterials including clarithromycin, tetracycline compounds, oral forms of miconazole (see section 2), trimethoprim and chloramphenicol
- Alcohol or medicines containing alcohol.
- Hormones such as testosterone or octreotide
- Medicines used to treat gout (e.g. sulfinpyrazone).
- St. John's Wort – *Hypericum perforatum* – preparations
- Fluoroquinolones (see Warnings and Precautions)

The following medicines may increase blood glucose levels. If you start treatment with any of these your dose of Gliclazide Tablets may therefore need to be increased:

- Medicines to treat disorders of the central nervous system (Antipsychotics e.g. chlorpromazine).
- Medicines reducing inflammation (Corticosteroids, e.g. hydrocortisone, prednisolone).
- Medicines to treat asthma or used during labour (intravenous salbutamol, ritodrine and terbutaline).
- Medicines to treat breast disorders, heavy menstrual bleeding and endometriosis (danazol).
- Medicines which increases urine flow (Diuretics, especially thiazide diuretics, e.g. bendroflumethiazide).
- Oral contraceptives e.g. oestrogens and progesterones.
- Rifamycins (antibacterial medicine)
- Adrenocorticotrophic hormones (ACTH) used in the treatment of adrenal insufficiency of central origin.e.g. tetracosactrin.

Gliclazide Tablets increases the effect of medicines which reduce blood clotting (Anticoagulants, e.g. warfarin).

The effect of gliclazide may be diminished when taken along with Diazoxide (for high blood pressure).

The effect of gliclazide may be diminished when taken along with phenothiazines.

### **Gliclazide Tablets with food, drink and alcohol**

Gliclazide Tablets should be taken before food , either with breakfast or the first main meal of the day. Drinking alcohol can alter the control of your treatment for diabetes and should be avoided.

If you have any questions or doubts about taking Gliclazide Tablets, you should consult your doctor or pharmacist.

### **Pregnancy and breast-feeding**

Gliclazide Tablets is not recommended for use in pregnancy. If you are pregnant, or planning to become pregnant or breast-feeding, 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 gliclazide tablets while you are breast feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

### **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).

### **Important information about some of the ingredients of Gliclazide Tablets**

#### **Gliclazide Tablets contain lactose.**

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

## **3. How to take Gliclazide tablets**

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

The usual dose is as mentioned below:

#### **Adults:**

The total daily dose may vary from one half to four tablets daily taken orally. This depends on the response to treatment. Change in external factors (weight reduction, change in life style, stress) or improvements in the blood sugar control may require changed gliclazide doses. You should not take more than two tablets at a time. When the total daily dose exceeds two tablets, it should be divided into two equal doses taken morning and evening.

#### **Elderly:**

The total daily dose may vary from one half to four tablets daily taken orally. The dose may be increased by your doctor if your blood sugar level does not come down enough. You should not take more than two tablets at a time. When the total daily dose exceeds two tablets, it should be divided into two equal doses taken morning and evening.

**Obese:** Additional therapy may also be required.

## **Children**

**Gliclazide tablets should not be used in children.**

These tablets should be taken as instructed, followed by a glass of water before meals. You should continue to take these tablets for as long as your doctor tells you to. Treatment for diabetes is usually life-long.

If a combination therapy of Gliclazide 80mg 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 swallows several of these tablets all together, or you think a child has swallowed any of these tablets, contact your doctor or pharmacist or hospital emergency department immediately. Always take any tablets left over with you, also the box and leaflet as this will allow easier identification of the tablets.

The symptoms to be expected of overdose are those of low sugar in the blood (hypoglycaemia) Symptoms include sweating, pale colour of the skin (pallor), hunger pangs, Increased heart beats(tachycardia) and malaise. These symptoms can be helped by taking glucose or sweet drinks. 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 80mg, 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

### **Other side effects**

- **Digestive disorders:** Abdominal pain or discomfort, nausea, vomiting, indigestion, diarrhoea and constipation. These effects are reduced when Gliclazide tablets are 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 (for example, the potentially fatal Stevens-Johnson syndrome or toxic epidermal necrolysis). 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 (for instance 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 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](http://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.**

Do not store above 25°C. Store in the original package.

Do not use your tablets after the expiry date stated on the label or carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how 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, pregelatinised maize starch, colloidal anhydrous silica, magnesium stearate and purified talc (*see section 2 for Important information about some of the ingredients of Gliclazide Tablets*).

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

Gliclazide Tablets are white, round, flat, uncoated, with bevelled edges debossed 'GZ/80' with break line on one side and plain on the other side.

They are available in blister pack of 28, 30, 56 or 60 tablets (Not all pack sizes may be marketed).

### **Marketing Authorisation Holder and Manufacturer**

Accord Healthcare Limited,  
Sage House, 319 Pinner Road,  
North Harrow, Middlesex,  
HA1 4HF, United Kingdom

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