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Gliclazide 80mg Tablets

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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, please 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:

- What Gliclazide Tablets are and what they are used for
- What you need to know before you take Gliclazide Tablets
- How to take Gliclazide Tablets
- Possible Side Effects
- How to Store Gliclazide Tablets
- Contents of the pack and other information

1. WHAT GLICLAZIDE TABLETS ARE AND WHAT THEY ARE USED FOR

- The name of your medicine is Gliclazide 80mg Tablets. The active ingredient is Gliclazide. Gliclazide belongs to a group of medicines called sulphonylureas that work by lowering the blood glucose (sugar) level.
- Non insulin dependent diabetes (type 2) in adults when dietary measures, physical exercise and weight loss alone are not sufficient to control blood glucose.

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 80 mg Tablets (listed in section 6), to other medicines of the same group (sulphonylureas), to other related medicines (hypoglycaemic sulphonamides),
- if you have insulin-dependant 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 **Other medicines and Gliclazide Tablets**),
- if you are breast-feeding (see **Pregnancy and breast-feeding**).

Children and adolescents
Gliclazide Tablet 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 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 for 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 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.

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. sulphonamides, clarithromycin),
- medicines to treat high blood pressure or heart failure (beta blockers, Antiarrhythmics, 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.

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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.

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 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 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 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 these tablets exactly as advised by your doctor. You should check with your doctor or pharmacist if you are not sure.

Change in external factors (weight reduction, change in life style, stress) or improvements in the blood sugar control may require changed gliclazide doses. The recommended daily dose is from 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 is 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

- Contact your nearest hospital casualty (A&E) or your doctor immediately.
- If you take too many tablets it may cause hypoglycaemia (too low a level of blood sugar); symptoms may include weakness, headache, sweating, feelings of hunger, raised pulse rate, breathlessness, tremor, problems with vision, loss of muscle co-ordination or anxiety.
- This condition can be improved by taking glucose or sweet drinks.
- Take your medicine in its original packaging with you in order to enable the doctor to identify your medication easily.

If you forget to take Gliclazide Tablets:

- Take the missed dose as soon as you remember and then take your next dose when it is due. Do not take a double dose to make up for the 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, Gliclazide Tablets 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, diarrhea and constipation. These effects are reduced when Gliclazide Tablet 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 (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 (for instance 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. 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 reach and sight of children.
- Blisters and Containers: This medicinal product does not require any special storage conditions.
- Do not use this medicine after the expiry date (EXP) which is stated in the carton. 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
- The other ingredients are lactose monohydrate, maize starch, croscarmellose sodium, colloidal anhydrous silica, purified talc and magnesium stearate.

What Gliclazide Tablets look like and contents of the pack

- Gliclazide 80mg Tablets are white to off-white, circular, flat faced beveled edge, uncoated tablets with cross break line on one side and plain on other side.
- The tablet can be divided into equal doses.
- Gliclazide 80 mg Tablets are available in blister packs of 28 and 60 tablets.

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If you would like this leaflet in different format information or want to report any side effects, please contact marketing authorization holder listed above.

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