

PACKAGE LEAFLET: INFORMATION FOR THE USER

Glibenclamide 2.5mg Tablets Glibenclamide 5mg Tablets (Glibenclamide)

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Glibenclamide Tablets are and what they are used for
2. Before you take Glibenclamide Tablets
3. How to take Glibenclamide Tablets
4. Possible side effects
5. How to store Glibenclamide Tablets
6. Further information

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

Glibenclamide belongs to a group of medicines known as oral hypoglycaemics which are used for the treatment of diabetics who do not need insulin but who need more than just diet to control their diabetes.

2. BEFORE YOU TAKE GLIBENCLAMIDE TABLETS

Do not take Glibenclamide Tablets:

- If you are allergic (hypersensitive) to Glibenclamide
- If you have severe liver or kidney problems
- If you have severe thyroid or adrenal gland problems
- If you have ever had a diabetic coma
- When you are under unusual stress such as surgery, trauma or severe infection

Take special care with Glibenclamide Tablets:

When you are about to do strenuous exercise as this medicine can cause blood sugar levels to get too low, known as “hypoglycaemia”. Early warning symptoms of low blood sugar include faintness, sweating, trembling, confusion or headache. You will need to eat and drink something sugary quickly.

Ask your doctor for more information about the symptoms of hypoglycaemia and what you should do if it happens. It is important that relatives and close workmates know that you have diabetes and are taking medication so that they can recognize the symptoms of hypoglycaemia and help if necessary.

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

The dose of Glibenclamide may need to be reduced if you are taking the following:

- drugs which are used to treat infections e.g. *fluconazole*, *sulphonamides*
- pain killers e.g. aspirin, phenylbutazone
- blood thinning agents e.g. *heparin*
- cholesterol lowering agents e.g. *clofibrate*
- anti-depressants e.g. *MAOIs*, *nortriptyline*
- drugs for high blood pressure and heart failure e.g. *captopril*, *enalapril*
- medicines for stomach ulcers and dyspepsia e.g. *cimetidine*, *ranitidine*
- drugs for obesity and gout

The dose of Glibenclamide may need to be increased if you are taking the following:

- rifampicin.
- tablets for getting rid of water in the body.
- drugs for high blood pressure and heart trouble.
- some products purchased at the chemists may have a high sugar content which may raise blood sugar levels.

Taking Glibenclamide Tablets with food and drink:

Glibenclamide should be taken with or immediately after food.

Alcohol may cause flushes in some patients and can affect the levels of sugar in your blood.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, planning to become pregnant or breast-feeding.

Do not breastfeed whilst on Glibenclamide Tablets without advice from your doctor.

Effects on the ability to drive and use machines:

If you experience the symptoms of low blood sugar (hypoglycaemia) 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. When your blood sugar is stabilized you may drive or operate machinery.

Important information about some of the ingredients of Glibenclamide Tablets

These tablets contain lactose so take care if you have been told by your doctor that you have intolerance to some sugars such as lactose.

3. HOW TO TAKE GLIBENCLAMIDE TABLETS

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

These tablets should be taken orally once a day with or immediately after breakfast or the first main meal of the day.

The usual starting dose for Glibenclamide is 2.5 – 5mg which can be increased if necessary. Your doctor will decide the dose which is best for you.

You should continue to take these tablets for as long as your doctor tells you to.

If you take more Glibenclamide than you should

If you accidentally take too many Glibenclamide Tablets seek immediate medical advice by contacting your doctor or nearest hospital casualty department.

If you forget to take Glibenclamide Tablets

If you forget to take a dose, take the missing dose as soon as you remember, with your next meal. If it is time for the next dose do not double the dose to make up for the one you missed.

If you stop taking Glibenclamide Tablets

Do not stop taking this medicine without consulting your doctor or pharmacist.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines Glibenclamide Tablets can cause some side effects although not everybody gets them.

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

- Allergic reactions (including inflammation of blood vessels, often with skin rash) which may develop into serious reactions with difficulty in breathing, fall in blood pressure and sometimes progressing to shock.
- Abnormal liver function including yellowing of the skin and eyes (jaundice) problems with the bile flow (cholestasis), inflammation of the liver (hepatitis) or liver failure,
- Allergy (hypersensitivity) of the skin such as itching, rash, hives and increased sensitivity to sun. Some mild allergic reactions may develop into serious reaction, which causes severe blistering of the skin, mouth, eyes and genitals.
- Severe hypoglycaemia including loss of consciousness, seizures or coma. Some patients experienced the following side effects whilst taking this medicine. Tell your doctor if you experience any of the following symptoms:

Rare side effects (affects more than 1 patient in 10,000 and less than 1 patient in 1000 people)

- Lower blood sugar than normal (hypoglycaemia) (See Section 2 - Take special care with Glibenclamide)
- Decrease in the number of blood cells:
- Blood platelets (which makes infections more likely)
- Red blood cells (which can make the skin pale and cause weakness or breathlessness)

Very rare (affects less than 1 patient in 10,000)

- Stomach upsets such as nausea, vomiting, abdominal pain, diarrhoea, loss of appetite or a metallic taste. Taking doses with food may reduce these problems.

They often get better spontaneously so you should continue to take the tablets unless your stomach is upset and shows no sign of getting better after a few days.

- Increased appetite and weight gain
 - decrease in the amount of sodium level in your blood (shown by blood tests)
- if any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE GLIBENCLAMIDE TABLETS

Keep out of the reach and sight of children.

Do not use your medicine after the expiry date shown on the label.

The expiry date refers to the last day of the month.

These tablets should not be stored above 25°C and should be kept in their original container to protect them from light and moisture.

Medicines should not be disposed of via wastewater or household water. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

What Glibenclamide Tablets contain:

The active substance is Glibenclamide.

The 2.5mg tablet contains 2.5mg of glibenclamide and the 5.0mg tablet contains 5.0mg glibenclamide.

The other ingredients are lactose, maize starch, povidone K30 and magnesium stearate.

What Glibenclamide Tablets look like and the contents of the pack:

Glibenclamide 2.5mg Tablets are white, circular tablets marked CP on one face and GL2.5 on the other.

The registered pack sizes are 10, 14, 28, 100, 500 and 1000 tablets.

Glibenclamide 5mg Tablets are white, capsule-shaped tablets marked CP on one face and GL5 on either side of a breakline, on the other face.

The registered pack sizes are 28, 100, 500 and 1000 tablets.

Marketing Authorization Holder and Manufacturer

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