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Ennogen Pharma

PACKAGE LEAFLET: INFORMATION FOR THE USER

Glibenclamide 2.5mg and 5mg 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, 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- What Glibenclamide Tablets are and what they are used for
- What you need to know before you take Glibenclamide Tablets
- How to take Glibenclamide Tablets
- Possible side effects
- How to store Glibenclamide Tablets
- Contents of the pack and other information

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

Glibenclamide Tablets belong to a group of therapeutic medicines called sulphonylureas which are used for lowering your blood sugar. Glibenclamide Tablets are used for treatment of patients with Type II maturity onset and non-insulin dependent diabetes that do not respond adequately to diet changes alone.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE GLIBENCLAMIDE TABLETS

Do not take Glibenclamide Tablets if you:

- Are allergic to glibenclamide or any of the other ingredients of this medicine (listed in section 6)
- Have type 1/juvenile diabetes or your diabetes is not stabilised
- Have diabetes and have had ketosis or have experienced diabetic coma
- Have thyroid problems
- Have kidney problems or liver disease
- Have functional problems with your adrenal glands
- Are pregnant, after delivery of your baby glibenclamide therapy may be started or resumed
- Have a blood condition called porphyria
- Are breastfeeding
- Are currently being treated with the medicine bosentan
- Have insulin dependant diabetes
- Are under unusual stress such as surgery, trauma or severe infection.

You should talk to your doctor before taking this medicine if you are going to have an operation, if you have a serious accident or severe infection, which can affect your diabetes.

Warnings and precautions

Talk to your doctor or pharmacist before taking Glibenclamide Tablets if you:

- Start to have symptoms of jaundice such as yellowing of the eyes and skin. Your doctor may stop your medication
- Are seriously ill or malnourished as taking this medicine may lower your blood sugar too much
- Are about to do strenuous exercises 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
- Have been told that you have problems with your adrenal or pituitary glands
- Have kidney problems, your doctor may give you a lower dose and monitor your response to Glibenclamide Tablets

- Are elderly. Patients aged 65 years and older are particularly sensitive to hypoglycemic action of glibenclamide and are therefore more at risk of hypoglycaemia. In the elderly, low blood sugar may be somewhat difficult to recognise. The initial dose and the maintenance dose of glibenclamide, must be set by your doctor carefully in order to avoid hypoglycemic reactions.

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 work mates know that you have diabetes and are taking medication so that they can recognize the symptoms of hypoglycaemia and help if necessary.

Other medicines and Glibenclamide Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, even those not prescribed.

In particular tell your doctor if you are taking a medicine called **bosentan** which is used to treat high blood pressure.

These medicines may increase the effect that glibenclamide has on lowering your blood sugar:

- Anabolic steroids** e.g nandrolone
- Medicines used to treat heart conditions such as **ACE inhibitors** or **beta-blockers** e.g captopril, atenolol
- Analgesics** used to treat pain e.g aspirin, paracetamol and other Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen
- Anticoagulants** to reduce blood clotting e.g warfarin and coumarin derivatives
- Antibacterials** or **antifungals** e.g fluconazole, miconazole, sulphonamides, chloramphenicol
- Cimetidine used to treat ulcers
- Sulphinpyrazone used to treat gout
- Medicines used to treat arthritis e.g cyclophosphamide, phenylbutazone
- Medicines used to treat tuberculosis
- Anti-depressants** e.g. MAOIs, nortriptyline
- Medicines used to reduce weight e.g fenfluramine.

These medicines may decrease the hypoglycaemic effect of glibenclamide:-

- Diuretics** e.g thiazide diuretics, furosemide, ethacrynic acid
- Phenothiazines** used to treat schizophrenia
- Oral contraceptives** containing oestrogen
- Corticosteroids**
- Rifampicin**, an antibiotic used to treat infections
- Ciclosporin**, a medicine used after organ transplants.

These medicines may lower the body's tolerance to glucose:

- Calcium blockers** used to treat heart conditions
- Lithium** used to treat depression.

Glibenclamide Tablets with food and alcohol

Glibenclamide Tablets should be taken with or immediately after food. Drinking alcohol while taking this medicine may affect the way it works. Talk to your doctor if you want to drink alcohol while taking this medicine.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice if you are pregnant or planning on becoming pregnant before taking this medicine. Consult your doctor if you are breast-feeding or plan to breast-feed as small amounts of this medicine may pass into the mother's milk.

Driving and using machines

This medicine may make you feel dizzy, shaky, confused, weak and sleepy. These are some of the signs of low blood sugar. If you experience any of these then you should not drive or operate machinery.

Glibenclamide Tablets contain lactose

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

3. HOW TO TAKE GLIBENCLAMIDE TABLETS

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth
- Take with or immediately after food.

The usual dose for:

New diabetics: Patients should be started with 5mg daily or 2.5mg with elderly or ill patients. The doses may be increased by 2.5mg at intervals of one week as directed by your doctor. The maximum daily dose is 15mg.

Patients changing from other sulphonylureas: The transfer can usually be carried out without a break in treatment. Initial treatment with glibenclamide is 5mg daily. If necessary this can be increased in steps of 2.5mg or 5mg. A dose of 5mg glibenclamide is equivalent to 1,000mg tolbutamide, 250mg chlorpropamide, 25mg glibornuride and 5mg glibipide.

Patients changing from biguanides: Glibenclamide treatment should be started with 2.5mg of glibenclamide and biguanide withdrawn. The dosage should then be adjusted by increments of 2.5mg to achieve control.

Use in children

Glibenclamide Tablets are unsuitable for children.

If you take more Glibenclamide Tablets than you should

This medicine is to be taken at regular intervals, as determined by the physician. If you take too many tablets by mistake contact your nearest hospital casualty department or tell your doctor immediately. Take your tablet pack with you. Low blood sugar (hypoglycaemia) may be treated in the conscious patient by administration of glucose or 3 or 4 lumps of table sugar in water. If the patient is comatose, glucose can be administered as an intravenous infusion.

If you stop taking Glibenclamide Tablets

Keep taking your tablets until your doctor tells you to stop. Do not stop taking your tablets just because you feel better. If you stop taking this medicine your symptoms may come back.

If you forget to take Glibenclamide Tablets

If you have forgotten to take a dose, leave out that dose completely. Do not take a double dose to make up for a forgotten dose. Take your next dose at the normal time. If you have trouble remembering to take the tablets, tell 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, this medicine can cause 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
- Allergic skin rashes may also occur such as erythema multiforme (red bullseye/target lesions with dark centre surrounded by pale pink ring and bright red outer ring, which may appear on the palms or soles of the feet). Stevens-Johnson syndrome (rash with flushing, fever, blisters or ulcers), toxic epidermal necrolysis (reddening, peeling and swelling that resembles burns), exfoliative dermatitis (peeling of the skin over large areas of the body) and erythema nodosum (red lumps underneath the skin surface)
- Severe hypoglycaemia including loss of consciousness, seizures or coma. Other signs of severe hypoglycaemia can include sweating, clammy skin, anxiety, high blood

pressure, chest pains (angina) and faster, stronger or irregular heart beat.

- There have been reports of changes to the blood including thrombocytopenia, agranulocytosis and anaemia. If you notice that you have started to bruise more easily, you have bleeding gums or you bleed for a long time after injury and you feel very tired and are pale, you should contact your doctor as soon as possible. If you become more susceptible to infections and develop mouth and throat ulcers, you should contact your doctor straight away.

Some patients have experienced the following side effects whilst taking this medicine.

Tell your doctor if you experience any of the following:

- Lower blood sugar than normal (hypoglycaemia) (see section 2)
- 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 in your blood (shown by blood tests)
- Temporary vision problems
- Sensitivity to light (photosensitivity)

If any of the side effects get serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 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 GLIBENCLAMIDE TABLETS

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the carton or label. The expiry date refers to the last day of that month.

Store below 25°C. Store in the original package in order to protect from light.

In case of any visible signs of deterioration, you should discard the package.

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 Glibenclamide Tablets contain

The active substance is glibenclamide. Each 2.5mg and 5mg tablet contains 2.5mg and 5mg of glibenclamide respectively.

The other ingredients are: lactose (see section 2), maize starch, gelatin, sodium carboxymethylcellulose, talc and magnesium stearate.

What Glibenclamide Tablets look like and contents of the pack

Glibenclamide Tablets 2.5mg have G1 on one side and a break line on the other side. Glibenclamide Tablets 5mg have G2 on one side and plain on the other side.

Glibenclamide Tablets are available in packs containing 28, 30, 56, 60, 84, 90, 100, 112, 120, 250, 500 and 1000 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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