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GLIBENCLAMIDE 2.5 mg OR 5 mg TABLETS

PACKAGE LEAFLET: INFORMATION FOR THE USER

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. Do not pass it on to others. It may harm them, even if their symptoms 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.

IN THIS LEAFLET:

1. What Glibenclamide is and what it is used for
2. What you need to know before you take Glibenclamide
3. How to take Glibenclamide
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1 WHAT GLIBENCLAMIDE IS AND WHAT IT IS USED FOR

Glibenclamide is an anti-diabetic drug.

Glibenclamide tablets are used in the management of non-insulin dependent diabetes to lower the level of sugar in the blood. They are used in cases where diet alone does not provide sufficient control.

2 BEFORE YOU TAKE GLIBENCLAMIDE

Do NOT take Glibenclamide if you:

- are allergic (hypersensitive) to Glibenclamide or any of the other ingredients of this medicine
- have a serious problems with your kidneys, liver, adrenal glands or pituitary gland
- are about to undergo any form of surgery
- have a severe infection
- have porphyria (Symptoms you may feel are like abdominal pain, mental confusion, anxiety, fits, muscle pain etc.)
- have juvenile or insulin-dependent diabetes
- are in trauma or suffering from stress.
- suffering from a history of diabetic ketoacidosis (presence of ketones in the urine) or diabetic coma or pre-coma.
- are elderly (Age over 70 years).

These tablets should not be used in patients suffering from or with a history of diabetic ketoacidosis (presence of ketones in the urine) or diabetic coma.

Warnings and precautions

Talk to your doctor before you start to take this medicine if you:

- are weak or feeble as you are more likely to suffer from a "hypo" (low blood-sugar attack)
- have a controlled diet or you take less calorie food or glucose
- have irregular meal time or you miss your meals often
- are doing excessive exercise
- If you have G6PD- deficiency (G6PD is an enzyme which protects red blood cells in blood). Please speak to your doctor if you are not sure about it.
- are debilitated.
- have lapp lactose deficiency (you are unable to digest milk or milk product)
- have mild to moderate kidney problems.

If you have jaundice (yellowing of skin and whites of the eyes) then please discontinue this medicine. Speak to your doctor in this case.

Other medicines and Glibenclamide

Talk to your doctor if you are taking any of the following:

- laxatives (used for loosening stools)
- chloramphenicol, isoniazid (used for the treatment of bacterial infection)
- tetracycline antibiotics e.g. doxycycline
- quinolone antibacterials e.g. ciprofloxacin
- sulphonamides e.g. co-trimoxazole
- miconazole, fluconazole (an anti-fungal drug)
- phenylbutazone, azapropazone (a non-steroidal anti-inflammatory drug)
- treatment for psychological disorders, e.g. chlorpromazine, lithium
- antidepressants e.g. fluoxetine or a monoamine oxidase inhibitor e.g. phenelzine
- fenfluramine (an appetite suppressant)
- anti-ulcer medicine e.g. ranitidine or cimetidine
- diuretics ("water tablets") e.g. furosemide or amiloride
- anabolic steroids e.g. nandrolone or stanozolol
- corticosteroids e.g. cortisone or prednisolone
- oral contraceptives ("the Pill")
- sex hormone for the treatment purpose e.g. testosterone, oestrogens, progesterones
- regular doses of aspirin
- phenylbutazone (used to treat pain, fever and inflammation of the body)
- ACE inhibitors (used to treat high blood pressure and heart failure) e.g. captopril or enalapril
- anti-coagulants e.g. warfarin or heparin
- disopyramide (used to treat irregular heart rhythms)
- clofibrate, nicotinic acid and bezafibrate (all used to lower fat levels in the blood)
- sulfinpyrazone, allopurinol, probenecid (used to treat gout)
- phenytoin (an anti-convulsant)
- rifampicin (an anti-tuberculosis drug)
- cyclophosphamide (an anti-cancer drug)
- bronchodilators (for asthma treatment) e.g. salbutamol
- thyroid hormone treatment
- diazoxide or glucagon (used to treat hypoglycaemia).
- bosentan (used to treat high blood pressure)
- crisantaspase (used to treat cancer)
- alcohol
- quinine, quinidine (used to treat malaria)
- clofibrate (used to treat blood cholesterol)
- cyclosporin (used to suppress immune system).

If you are taking clonidine or guanethidine (used to reduce high blood pressure), or a beta-blocker, e.g. propranolol, you should be aware that these drugs may affect the warning signs of a "hypo" (low blood sugar attack).

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

Important information about some of the ingredients of Glibenclamide

- Patients who are intolerant to lactose should note that Glibenclamide tablets contain a small amount of lactose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Pregnancy and breast-feeding

Do NOT use Glibenclamide if you are pregnant or planning to become pregnant. Speak to your doctor before taking any medicine.

You should let your doctor know as soon as possible if you are breast feeding or you want to start breast-feeding whilst taking these tablets.

Driving and using machines

Glibenclamide is not known to affect your ability to drive or operate machinery unless you have very low blood sugar which makes you feel very sick.

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3 HOW TO TAKE GLIBENCLAMIDE

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

The tablets should be swallowed preferably with a drink of water. The usual dose is:

• Adults

The starting dose is 5 mg a day, taken during or straight after breakfast (or the first main meal of the day). This may then be adjusted by your doctor, to a maximum of 15 mg a day.

• Elderly and very frail patients

The normal adult starting dose should be reduced to 2.5 mg a day.

• Changing from another anti-diabetic medicine

The starting dose is 5 mg to 10 mg a day, depending on your previous dosage. This may then be increased by your doctor, to a maximum of 15 mg a day.

- If you are changing from metformin to Glibenclamide, your starting dose will be 2.5 mg a day and then adjusted as the metformin treatment stops, to a maximum of 15 mg a day. You may occasionally be required to take both types of medication at the same time, but your doctor will advise you of this.

- Similarly, if you are changing from insulin treatment to Glibenclamide, your starting dose will be 5 mg a day and then adjusted as the insulin treatment stops, to a maximum of 15 mg daily.

• Children

Glibenclamide is not recommended for use in children.

If you take more Glibenclamide than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately.

An overdose is likely to cause low blood sugar characterised by faintness, feeling sick, cold sweats, and/or palpitations.

Please take this leaflet, any remaining tablets, and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Glibenclamide

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do NOT take a double dose to make up for a forgotten dose. Take the remaining doses at the correct time.

If you stop taking Glibenclamide

Do NOT stop taking your medicine without talking to your doctor first even if you feel better.

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

4 POSSIBLE SIDE EFFECTS

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

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

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

Rare:

- Decrease in blood cells which places individuals at increased risk of infection.

Unknown:

- problems with your vision (at the beginning of your treatment only)

- loss of appetite, diarrhoea, feeling sick, vomiting, burning chest pain that is caused by stomach acidity, eating disorder
- jaundice (yellowing of skin and whites of the eyes)
- allergic skin reactions, rash, itching or skin sensitivity after light exposure
- skin cell death
- fever
- metallic taste in the mouth
- weight gain
- increased appetite
- swelling of limbs due to accumulation of water
- low sodium concentration in the blood (this can be detected from a blood test).

You may occasionally suffer from a "hypo" (low blood-sugar attack) relating to your dosage, diet and exercise, during which you may feel faint, sick and have cold sweats or palpitations. Your doctor will advise you what to do when you first start your treatment with Glibenclamide.

You may become allergic to other sulphonamide drugs, such as co-trimoxazole.

Rarely, blood disorders may occur, which may be characterised by pallor, fever or chills, sore throat, ulcers in your mouth or throat, unusual bleeding or unexplained bruising.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 GLIBENCLAMIDE**Keep out of the reach and sight of children.**

Do not store above 25°C. Keep in the original package or container supplied. Do not transfer them to another container.

Do not use Glibenclamide after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month. 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 Glibenclamide tablets contain:**

- The active ingredient is Glibenclamide.
- The other ingredients are lactose anhydrous, croscarmellose sodium and magnesium stearate (E572).

What Glibenclamide tablets look like and contents of the pack:

- The Glibenclamide 2.5 mg tablets are white, biconvex tablets. They are engraved '2.5' over '3103' on one side and plain on the reverse.
- The Glibenclamide 5 mg tablets are white, oval, biconvex tablets. They are engraved '5' breakline '3104' on one side and plain on the reverse.
- The product is available in pack sizes of 7, 10, 14, 21, 28, 30, 56, 60, 84, 90, 100, 110, 112, 120, 150, 160, 168, 250, 500, and 1000 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation holder and company responsible for manufacture is TEVA UK Limited, Eastbourne, BN22 9AG.

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