

PACKAGE LEAFLET: INFORMATION FOR THE USER**Glibenclamide 2.5 mg Tablets**

Glibenclamide

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 side effects, talk to your doctor or your pharmacist. This includes any possible side effects not listed in this leaflet.

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.
4. Possible side effects.
5. How to store Glibenclamide.
6. Contents of the pack and other information.

1. What Glibenclamide is and what it is used for

The name of your medicine is Glibenclamide 5 mg Tablets

Glibenclamide is a medicine taken by mouth to help lower blood sugar. It belongs to a group of medicines called sulfonylureas.

Glibenclamide works by increasing the amount of insulin released from your pancreas. The insulin then lowers your blood sugar levels.

What Glibenclamide is used for

- Glibenclamide is used to treat a certain form of diabetes (type 2 diabetes mellitus), when diet, physical exercise and weight reduction alone have not been able to control your blood sugar levels.

2. What you need to know before you take Glibenclamide Tablets**Do not take Glibenclamide Tablets if:**

- You are allergic (hypersensitive) to glibenclamide, sulphonamides (medicines for bacterial infection) or any of the other ingredients of Glibenclamide.
- You have insulin dependent diabetes (type 1 diabetes mellitus)
- You have diabetic ketoacidosis (a complication of diabetes with some of the following signs: fatigue, nausea (feeling sick), frequent urination and muscular stiffness)
- You are in diabetic coma
- You are pregnant
- You are breast-feeding
- You have severe problems with your kidneys
- You have a severe liver disease
- You are receiving a medicine called bosentan used to treat high blood pressure.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking glibenclamide.

Warning and Precautions

Take special care with Glibenclamide Tablets

Check with your doctor or pharmacist before taking your medicine if:

- You are recovering from an injury, operation, infections with fever, or from other forms of stress, inform your doctor as temporary change of treatment may be necessary
- You have a severe liver or kidney disorder

If you are not sure if any of these apply to you, talk to your doctor or pharmacist before taking glibenclamide.

Lowering of the haemoglobin level and breakdown of red blood cells (haemolytic anemia) can occur in patients missing the enzyme glucose-6-phosphate dehydrogenase.

Epidemiological studies suggest an increased of cardiovascular mortality with administration of glibenclamide, when compared to metformin or gliclazide. The risk was especially observed in patients with diagnosed coronary (heart) diseases.

Children

The information available on the use of glibenclamide in people under 18 years of age is limited. Therefore glibenclamide is not recommended for use in children.

Important information about hypoglycaemia (low blood sugar)

When you take glibenclamide, you may get hypoglycaemia (low blood sugar). Please see below for additional information about hypoglycaemia, its signs and treatment.

Following factors could increase the risk of you getting hypoglycaemia:

- Undernourishment, irregular meal time, missed or delayed meal or period of fasting
- Changes to your diet
- Taking more glibenclamide than needed
- Having kidneys that do not work properly
- Having severe liver disease
- If you suffer from particular hormoneinduced disorders (disorders of the thyroid glands, of the pituitary gland or adrenal cortex)
- Drinking alcohol (especially when you skip a meal)
- Taking certain other medicines (See Taking other medicines below)
- If you increase the amount of exercise you do and you don't eat enough food or eat food containing less carbohydrate than usual.
- If you are elderly or have adrenal or pituitary insufficiency

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.

Signs of hypoglycaemia include:

- Hunger pangs, headache, nausea, vomiting, sluggishness, sleepiness, problems sleeping, restlessness, aggression, problems with concentration, reduced alertness and reaction time, depression, confusion, problems with your speech and sight, slurred speech, shakiness, partial paralysis, dizziness, helplessness
- The following signs may also occur: sweating, clammy skin, anxiety, fast or increased heart beat, high blood pressure, awareness of your heart beat, sudden strong pain in the breast that may radiate into neighbouring

areas (angina pectoris and cardiac arrhythmias). If blood sugar levels continue to drop you may suffer from considerable confusion (delirium), develop fits, lose self control, breathing may be shallow and your heart beat slowed down, you may fall into unconsciousness. The clinical picture of a severe reduced blood sugar level may resemble that of a stroke.

Treating hypoglycaemia:

In most cases the signs of reduced blood sugar vanish very quickly when you consume some form of sugar, e.g. sugar cubes, sweet juice, sweetened tea. You should therefore always take some form of sugar with you (e.g. sugar cubes).

Remember that artificial sweeteners are not effective.

Please contact your doctor or go to the hospital if taking sugar does not help or if the symptoms recur.

Laboratory Tests

The level of sugar in your blood or urine should be checked regularly. Your doctor may also take blood tests to monitor your blood cell levels and liver function.

Other medicines and Glibenclamide

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Your doctor may wish to change your dose of glibenclamide if you are taking other medicines, which may weaken or strengthen the effect of glibenclamide on the level of sugar in your blood.

The following medicines can increase the blood sugar lowering effect of glibenclamide. This can lead to a risk of hypoglycaemia (low blood sugar):

- Other medicines to treat diabetes mellitus (such as insulin)
- Medicines to treat pain and inflammation (phenylbutazone, azopropazone, oxyphenbutazone)
- Medicines to treat urinary infections (such as some long acting sulfonamides)
- Medicines to treat bacterial and fungal infections (tetracyclines, chloramphenicol, fluconazole, miconazole, quinolones, clarithromycin)
- Medicines to inhibit blood clotting (coumarin derivatives such as warfarin)
- Medicines supporting muscle build up (anabolics)
- Medicines used for male sex hormone replacement therapy
- Medicines to treat depression (fluoxetine, MAO-inhibitors)
- Medicines lowering high cholesterol level (fibrates)
- Medicines lowering high blood pressure (ACE inhibitors)
- Medicines to treat gout (probenecid, sulfinpyrazone)
- Medicines to treat cancer (cyclophosphamide, ifosfamide, trofosfamide)
- Medicines used to reduce weight (fenfluramine)
- Medicines to increase circulation when given in a high dose intravenous infusion (pentoxifylline)
- Medicines to treat nasal allergies such as hay fever (tritoqualine)
- Medicines called sympatholytics to treat high blood pressure, heart failure, or prostate symptoms

The following medicines may decrease the blood sugar lowering effect of glibenclamide. This can lead to a risk of hyperglycaemia (high blood sugar level):

- Medicines containing female sex hormones (oestrogens, progestogens)
- Medicines to treat high blood pressure called thiazide diuretics (water tablets)
- Medicines used to stimulate the thyroid gland
- Medicines to treat allergies and inflammation (glucocorticoids)
- Medicines to treat severe mental disorders (phenothiazine derivatives)
- Medicines used to raise heart beat, to treat asthma or nasal congestion, coughs and colds, used to reduce weight, or used in lifethreatening emergencies (adrenaline and sympathomimetics)
- Medicines to treat high cholesterol level (nicotinic acid)
- Medicines to treat constipation when they are used long term (laxatives)
- Medicines to treat fits (phenytoin)

- Medicines to treat nervousness and sleep problems (barbiturates)
- Medicines to treat increased pressure in the eye
- Medicines to treat high blood pressure or lowering blood sugar (diazoxide)
- Medicines to treat infections, tuberculosis (rifampicin)
- Medicines to treat severe low blood sugar levels (glucagon)

The following medicines can increase or decrease the blood sugar lowering effect of glibenclamide:

- Medicines to treat stomach ulcers (called H2 antagonists)
- Medicines to treat high blood pressure or heart failure such as beta-blockers, clonidine, guanethidine and reserpine.

These can also hide the signs of hypoglycaemia, so special care is needed when taking these medicines

Glibenclamide may either increase or weaken the effects of the following medicines:

- Medicines inhibiting blood clotting (coumarin derivatives such as warfarin)

Taking Glibenclamide Tablets with food and drink

Alcohol intake may increase or decrease the blood sugar lowering action of Glibenclamide in an unpredictable way.

Pregnancy, breast-feeding and fertility

Glibenclamide should not be taken during pregnancy. Tell your doctor if you are, you think you might be or are planning to be pregnant.

Glibenclamide may pass into breast milk. Glibenclamide should not be taken during breast-feeding.

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

Driving and using machines

Your ability to concentrate or react may be reduced if your blood sugar is lowered (hypoglycaemia), or raised (hyperglycaemia) or if you develop visual problems as a result of such conditions.

Bear in mind that you could endanger yourself or others (e.g. when driving a car or using machines). Please ask your doctor whether you can drive a car if you:

- have frequent episodes of hypoglycaemia,
- have fewer or no warning signals of hypoglycaemia

Important information about some of the ingredients of Glibenclamide Tablets

Glibenclamide contains lactose. If you have been told by your doctor that you cannot tolerate some sugars, contact your doctor before taking this medicinal product.

3. How to take Glibenclamide Tablets

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

Taking this medicine

- Take this medicine by mouth, just before or with the first main meal of the day (usually breakfast). If you do not have breakfast you should take the product on schedule as prescribed by your doctor. It is important not to leave out any meal when you are on glibenclamide.
- Swallow the tablets whole with at least half glass of water. Do not crush or chew the tablets

How much to take

The dose of Glibenclamide depends on your needs, condition and results of blood and urine sugar tests and is determined by your doctor. Do not take more tablets than your doctor has prescribed.

- The usual starting dose is one 5mg tablet daily.
- If necessary, your doctor may increase the dose after each 1 - 2 weeks of treatment.
- If you are run down or are elderly, you will usually start by taking a lower dose.
- Your dose of Glibenclamide may need to be adjusted if you change weight, change your lifestyle, or if you are under a lot of stress. Please speak to your doctor if any of these situations apply to you.
- If you feel the effect of your medicine is too weak or too strong do not change the dose yourself, but ask your doctor.

If you take more Glibenclamide Tablets than you should

If you happen to have taken too much glibenclamide or an additional dose there is a danger of hypoglycaemia (signs of hypoglycaemia see Section 2 - Take special care with glibenclamide) and therefore you should instantly consume enough sugar (e.g. sugar cubes, sweet juice, sweetened tea) and inform a doctor immediately.

When treating hypoglycaemia due to accidental intake in children, the quantity of sugar given must be carefully controlled to avoid the possibility of producing dangerous hyperglycaemia. Persons in a state of unconsciousness must not be given food or drink.

Since the state of hypoglycaemia may last for some time it is very important that the patient is carefully monitored until there is no more danger. Admission into hospital may be necessary, also as a measure of precaution. Show the doctor the package or remaining tablets, so the doctor knows what has been taken.

Severe cases of hypoglycaemia accompanied by loss of consciousness and coma are cases of medical emergency requiring immediate medical treatment and admission into hospital. It may be helpful to tell your family and friends to call a doctor immediately if this happens to you.

If you forget to take Glibenclamide Tablets

If you forget to take a dose, do not take a double dose to make up for forgotten doses. Take your normal dose as soon as you remember and continue as normal. If you are unsure or are concerned contact your doctor to discuss.

If you stop taking Glibenclamide Tablets

If you interrupt or stop the treatment you should be aware that the desired blood sugar lowering effect is not achieved or that the disease will get worse again. Keep taking Glibenclamide until your doctor tells you to stop.

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.

Tell your doctor immediately if you experience any of the following symptoms:

- Allergic (hypersensitivity) reactions which may include:
 - Swelling of the lips, face, throat or tongue
 - Skin rash, itching, hives and increased sensitivity to the sun
 - Inflammation of blood vessels, often accompanied with skin rash, which may develop into serious reactions accompanied with difficulty 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.
- Severe hypoglycaemia including loss of consciousness, seizures or coma

Rare: may affect up to 1 in 1,000 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 increases risk of bleeding or bruising)
- White blood cells (which makes infections more likely)
- Red blood cells (which can make the skin pale and cause weakness or breathlessness)

These problems generally get better after you stop taking glibenclamide.

Very rare: may affect up to 1 in 10,000 people

- Feeling or being sick, diarrhoea, feeling full or bloated, and abdominal pain
- Decrease in the amount of sodium level in your blood (shown by blood tests)
- Problems with your sight may occur when beginning treatment with Glibenclamide. This is due to changes in blood sugar levels and should soon improve
- Increased liver enzymes

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL -Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this

5. How to store Glibenclamide Tablets

This medicinal product does not require any special storage conditions.

Keep this medicine out of the sight and reach of children.

Do not use Glibenclamide Tablets after the expiry date which is stated on the carton and on the label or blister. 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 to protect the environment.

6. Contents of the pack and other information

What Glibenclamide Tablets contain

The active substance is glibenclamide.

Glibenclamide 2.5 mg Tablets contain 2.5 mg of glibenclamide.

Other ingredients are: microcrystalline cellulose, lactose monohydrate, colloidal anhydrous silica, magnesium stearate and talc.

What Glibenclamide Tablets look like and contents of the pack

Glibenclamide 2.5 mg Tablets are plain, round, flat, bevelled edge white tablets with a breakline on one side.

Glibenclamide 2.5 mg Tablets come in blister packs of 20, 28, 30, 60 & 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder:
Chanelle Medical, Loughrea, Co Galway, Ireland.

The Manufacturer:
Chanelle Medical, Loughrea, Co Galway, Ireland.

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Other Sources of information

Detailed information on this medicine is available on the website of www.hpra.ie