

i PACKAGE LEAFLET:
Information for the user

GLIBENKLAMID

Tablets – 5 mg

(Glibenclamide)

Read 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 only. 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 worse or if you notice any side effect not listed in this leaflet, please inform your doctor or pharmacist.

In this leaflet:

1. What Glibenklamid is and what it is used for
2. Before you take Glibenklamid
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1. WHAT GLIBENKLAMID IS AND WHAT IT IS USED FOR

Glibenklamid is an oral hypoglycemic, derivative of the sulphonylurea. The decrease of blood glucose concentration happens because of the stimulation of insulin secretion by the pancreas. This action needs the presence of the beta functional cells. Glibenklamid is indicated in diabetes mellitus type II (non - insulin dependent diabetes).

Your doctor may have given Glibenklamid to you for another reason. Ask your doctor if you want to know why Glibenklamid has been given to you.

2. BEFORE YOU TAKE GLIBENKLAMID

Do not take Glibenklamid if you:

- are hypersensitive to the active substance glibenclamide, to the other sulphonylurea antidiabetics or to any of the other excipients of Glibenklamid tablets;
- have passed diabetic ketoacidosis or diabetic coma / precoma;
- suffer from insulin - dependent diabetes mellitus;
- suffer from serious renal impairment;
- suffer from serious hepatic or adrenocortical impairment;
- are passing an unusual stress period such as: surgery or pregnancy and breast - feeding, when insulin values are very important;
- suffer from acute porphyria;
- are being treated with bosentan.

Take special care with Glibenklamid

Ask your doctor before you take Glibenklamid if:

- you have renal or hepatic impairment which may increase the risk for hypoglycemia;
- you have high probability for the above effect such as: the elderly, malnourished patients and those suffering from adrenal or pituitary insufficiency;
- consume alcohol; its consume during treatment with glibenclamide should be discontinued, because it may cause hypoglycemia;
- you suffer from cardiovascular diseases;
- you have glucose - 6 phosphate dehydrogenase deficiency.

Taking other medicines

Concomitant treatment with other drugs may affect or be affected by Glibenklamid. Please contact your doctor or pharmacist if you are taking or have recently taken other drugs, including those without a prescription. Do not forget to inform your doctor for the treatment with Glibenklamid if you have been given any other drug during treatment. A decrease of the hypoglycemic effect may happen, which may require a higher dose of the sulphonylurea to result in the same effect, if Glibenklamid is administered concomitantly with:

- adrenaline;
- aminoglutethimide;
- chlorpromazine;
- corticosteroids;
- diazoxide;
- oral contraceptives;
- rifampicin;
- thiazide diuretics;
- thyroid hormones.

A greater hypoglycemic effect is noticed or is expected after the use of:

- ACE - inhibitors;
- alcohol;
- allopurinol;
- some analgesics like: azapropazone, phenylbutazone and salicylates;
- azoles like: fluconazole, ketoconazole and miconazole;
- chloramphenicol;
- cimetidine;
- clofibrate and similar compounds;
- coumarin anticoagulants;
- fluoroquinolones;
- heparin;
- MAO - I;
- octreotide (although it may also cause hyperglycemia);
- ranitidine;
- sulphipirazole;
- sulphonamides (including co - trimoxazole);
- tetracyclines;
- tricyclic antidepressants.

It is noticed that beta-blockers may increase hypoglycemia. There have been sporadic and controversial reports in terms of interaction with calcium - channel blockers, but finally it is concluded that there is no relevant clinical effect.

Taking Glibenklamid with food and drinks

Glibenklamid should not be taken with alcoholic drinks because their concomitant administration may cause hypoglycemia.

Pregnancy

Glibenklamid is not recommended to be used during pregnancy.

Breast - feeding

The use of Glibenklamid during breast - feeding should be avoided due to the risk of hypoglycemia in children.

Driving and using machinery

You should be careful from hypoglycemic attack during driving and using machinery. If you can not control the attack or you have recurrent episodes of hypoglycemia, you should not drive or use machinery.

Important information about some of the excipients of Glibenklamid

This drug contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE GLIBENKLAMID

Always take Glibenklamid exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. If you feel that the effects of Glibenklamid are too strong or too weak, talk to your doctor or pharmacist. The tablets should be swallowed with a glass of water (200 - 250 ml of water).

The posology is as follows:

The initial common dose in traditional formulations in diabetes mellitus type 2 is 2.5 - 5 mg daily with breakfast and increases every 7 days with 2.5 - 5 mg daily until 15 mg daily. Although it is not thought that doses over 15 mg increase the benefits, daily doses up to 20 mg daily are given. Daily doses greater than 10 mg can be given in two divided doses during the day.

Due to the long duration of action, it is not preferable for glibenclamide to be given to the elderly.

If you take more Glibenklamid than you should

If you take more Glibenklamid than you should, or if the children have taken this medicine incorrectly, please contact your doctor, the hospital or call the emergency to get an opinion for the risk and an advice for the actions to be taken.

Overdose from sulphonylureics including glibenclamide may cause hypoglycemia. Hypoglycemia may be treated in conscious patients by administering glucose or three - four sugar lumps (or common sugar) with water. This may be repeated whenever necessary. If the patient is in coma, glucose may be given in the form of an intravenous infusion and the patient should be under the supervision of the medical staff. Bolus glucose injections are not recommended because of the possibility of rebound hypoglycemia. Alternatively, 1 mg of glucagon may be administered subcutaneously or intramuscularly to restore patient consciousness.

If you forget to take Glibenklamid

If you forget a dose (or more doses), take the following dose when it is time to take it usually.

Do not take a double dose (or higher) to make up for a forgotten dose(s).

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

4. POSSIBLE SIDE EFFECTS

Like all other medicines, Glibenklamid may cause side effects, although not everybody manifests them. Glibenklamid is well tolerated in the recommended doses. Inform your doctor for the following side effects that may appear to you:

- gastrointestinal disorders such as: nausea, vomiting, heartburn, anorexia, diarrhea and a metallic taste which is dose - dependent; also increased appetite and weight gain may be noticed;
 - skin disorders such as: rash and pruritus, facial flushing;
 - visual disorders such as: photosensitivity;
 - hypoglycaemia;
 - hypersensitivity reaction that includes: altered liver enzyme values, hepatitis and cholestatic jaundice, leucopenia, thrombocytopenia, aplastic anaemia, agranulocytosis, haemolytic anaemia, erythema multiforme or Stevens - Johnson syndrome and exfoliative dermatitis;
 - water retention, hyponatraemia and CNS effects because of the inappropriate secretion of the antidiuretic hormone (SIADH).
- Glibenclamide may increase the cardiovascular mortality. This effect is still under discussion.

If any of the side effects worsens, or if you notice side effects not mentioned in this leaflet, please inform your doctor or pharmacist. When any of the above-mentioned side effects appears, treatment with Glibenklamid should be discontinued and you should consult with your doctor or pharmacist.

5. HOW TO STORE GLIBENKLAMID

Keep away from children.

Do not use Glibenklamid after the expiry date which is stated on the package.

Store below 25°C.

Store in the original packaging to protect it from light and humidity.

6. FURTHER INFORMATION

What Glibenklamid – tablets 5 mg contain:

The active substance is glibenclamide.

Each tablet contains 5 mg glibenclamide.

Other excipients are: lactose monohydrate, microcrystalline cellulose, magnesium stearate, talc.

Contents of the pack:

Carton box with 60 tablets.

Explanatory of the illustration icons on the packaging:



Ask your doctor or pharmacist.



Do not use this medicine during pregnancy.



Content.



Warning.



Tablet shape.

Marketing authorisation holder (MAH) and manufacturer:



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