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

Glibenklamid is an oral hypoglycemiant, derivative of the sulfonylurea. 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) that does not respond to strict diet, weight loss (for overweight patients) and exercise.

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 sulfonylurea antidiabetics or to any of the 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 breastfeeding, 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 are suffering from vomiting, diarrhoea or if you regularly use laxatives;
- 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;
- barbiturates and phenytoin;
- nicotinamide;
- acetazolamide;
- glucagon;
- laxatives (after prolonged use);
- phenotiazines;
- aminoglutethimide;
- chlorpromazine;
- corticosteroids;
- diazoxide;
- oral contraceptives;
- rifampycin;
- thiazide diuretics;
- thyroid hormones.

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

- insulin;
- anabolic steroids and male sexual hormons;
- medicines for cancer treatment (ciclophosphamide);
- appetite suppressants (fenfluramine);
- para-aminosalicylic acid;
- probenicid;
- pentoxiphylline (when administered intravenously and in high doses);
- tritoqualine;
- 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;
- sulphinpirazone;
- sulphonamides (including co - trimoxazole);
- tetracyclines;
- tricyclic antidepressants.

These medicines may increase or decrease the effect of glibenclamide:

- H_2-receptors antagonists;
- clonidine;
- reserpine.

Glibenclamide may:

- decrease or increase the effect of coumarine derivatives;
- increase the toxicity of ciclosporine (if these medicines are administered concomitantly, dose adjustment is necessary);
- be affected by colesevelam, which may decrease the absorbance of glibenclamide in the gut. For this reason, glibenclamide should be taken at least 4 hours before colesevelam.

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.

Breastfeeding

The use of Glibenklamid during breastfeeding 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), with food or immediately after food.

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.

Special populations:

Children and adolescents: Glibenklamid is not used in children and adolescents.

Elderly: even in low doses, Glibenklamid can cause hypoglycaemia, the doctor will decide for the right dose for the elderly.

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.

If you stop taking Glibenklamid

If you stop taking Glibenklamid because your symptoms improve, they may come back.

Do not stop taking Glibenklamid without consulting your doctor. If you have further questions on the use of this medicinal 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:

Common (affect up to 1 in 10 patients):

- Hypoglycaemia (lowering of the blood sugar level below 50 mg/dl); the symptoms include: headache, irrepressible hunger, nausea, vomits, fatigue, disturbed sleep, agitation, aggressiveness, decrease in concentration, in vigilance and in reaction, depression, confusion, aphasia, visual disturbances, tremor, paralysis, sensitivity disturbances, dizziness, feeling of helplessness, loss of self-control, delirium, convulsions, drowsiness, loss of consciousness till coma, shallow breathing, bradycardia, sweating, clammy skin, anxiety, palpitations, tachycardia, arrythmia, hypertension, angina pectoris);
- Weight gain.

Uncommon (affect up to 1 in 100 patients)

- Skin disorders, such as:
  - erythema, rash and pruritus, facial flushing;
  - photosensitivity;
  - urticaria, difficulty breathing, lowering of the blood pressure till shock.

- Gastrointestinal disorders, such as:
  - nausea;
  - vomiting;
  - heartburn;
  - anorexia;
  - diarrhea;
  - a metallic taste which is dose-dependent.

Rare (affect up to 1 in 1,000 patients)

- Blood disorders: thrombocytopenia.

Very rare (affect up to 1 in 10,000 patients)

- Blood disorders, such as:
  - erythrocytopenia;
  - lowering of the white blood cells: leucopenia, granulocytopenia, agranulocytosis;
  - aplastic anaemia;
  - haemolytic anaemia.

- Liver disorders, such as:
  - altered liver enzyme values;
  - hepatitis;
  - cholestatic jaundice.

- Hypersensitivity reaction that includes: Stevens-Johnson syndrome, joint and muscle pain, fever, proteinuria and hepatic disorders.
- Water retention, hyponatremia and effects on CNS due to inappropriate secretion of the antidiuretic hormone (SIADH).
- Blood vessels inflammation (allergic vasculitis), which may be life-threatening.

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 out of the reach and sight of 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 5 mg tablets contain:

The active substance is glibenclamide.

Each tablet contains 5 mg glibenclamide.

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

Contents of the pack:

Carton box with 60 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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