

GLIBENCLAMIDE **5 mg Tablets**

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about GLIBENCLAMIDE

Each GLIBENCLAMIDE tablet for oral administration contains 5 mg glibenclamide.

Glibenclamide is an oral antidiabetic agent, a second-generation sulfonylurea that stimulates the production and secretion of insulin from beta pancreatic cells, and promotes the uptake of sugar into body cells, so lowering the level of sugar in the blood.

GLIBENCLAMIDE is indicated as an adjunct to diet to lower the blood glucose level in patients with non-insulin dependent (Type 2) diabetes mellitus whose hyperglycemia cannot be controlled by diet alone.

The way to take GLIBENCLAMIDE

Take GLIBENCLAMIDE as directed by your doctor. Do not discontinue the treatment without consulting your physician.

The starting dose is 2.5 mg to 5 mg once daily for 5-7 days to be given in the morning with breakfast or with the first main meal; the dose is increased gradually, according to blood sugar levels.

The usual maintenance dose is in the range of 1.25 mg to 20 mg daily, which may be given as a single dose or in divided doses.

The majority of cases can be controlled by 5-10 mg per day and some may require up to 15 mg daily.

The maximum recommended dosage is 20 mg daily.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. Overdosage can produce hypoglycemia; mild hypoglycemic symptoms without loss of consciousness should be treated with oral sugar. Severe hypoglycemic reactions with coma and seizure require hospitalization.

In case of missed dose

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

Contraindications

This drug is contraindicated in the following conditions:

- Known hypersensitivity to any of the components or to other sulfonylureas,
- Unstable and/or insulin-dependent (type I) diabetes mellitus,
- Diabetic Ketoacidosis, with or without coma,
- In patients with serious renal or hepatic dysfunction,
- Pregnancy and lactation.

Precautions

-Periodic assessment of cardiovascular, dermatological, renal, hepatic and ophthalmic status is advisable.

-Severe hypoglycemia can be induced by all sulfonylurea; the use of carbohydrates (glucose or sugar) is required in case of acute episode.

-Long-term treatment may cause failure in the treatment, in this case, an adaptation of the posology or an adjuvant therapy must be considered.

-In the event of injury, surgery, infectious diseases, temporary insulin therapy may be installed in order to ensure adequate metabolic control.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

Hypoglycemia may be potentiated by certain drugs, including non-steroidal anti-inflammatory agents, salicylates, sulfonamides, chloramphenicol, probenecide, MAO inhibitors, beta adrenergic blocking agents clarithromycin, oral miconazole and fluoroquinolones antibiotics.

Hyperglycemia may be produced by diuretics, corticosteroids, thyroid products, phenytoin, estrogens, oral contraceptives, sympathomimetics, calcium channel blocking agents, isoniazid and nicotinic acid.

H₂receptor antagonists, clonidine and reserpine may lead to either potentiation or weakening of the blood-sugar-lowering effect.

This drug may either potentiate or weaken the effect of coumarin derivatives and may increase cyclosporine concentration.

The combination with bosentan is contra-indicated.

Adverse reactions

The most frequently reported side effects were: skin rashes, photosensitivity, diarrhea, nausea, vomiting, epigastric pain, feeling of gastric fullness, dizziness, headache, weakness, fever, hypoglycemic reactions and paresthesia. Hepatobiliary, hematological and endocrinological disorders may occur.

Please inform your doctor if any side effect appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 30°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

GLIBENCLAMIDE, 5 mg, pack of 100 tablets

Revision date: 04/2009

GLIT5/003