

Glucozid

Gliclazide BP

Composition

Glucozid Tablet: Each tablet contains Gliclazide BP 80 mg.

Glucozid MR 30 Tablet: Each modified release tablet contains Gliclazide BP 30 mg.

Glucozid MR 60 Tablet: Each modified release tablet contains Gliclazide BP 60 mg.

Pharmacology

Glucozid (Gliclazide) is a hypoglycemic agent of the sulfonylurea group. The hypoglycemic action of Gliclazide is related to an improvement in insulin secretion from the functioning beta cells of the pancreas. It potentiates the insulin release, improves the dynamics of insulin. Gliclazide has extra-pancreatic actions. These metabolic actions are accompanied by hemovascular effects.

Extra-pancreatic effects: It has been demonstrated that Gliclazide increases peripheral insulin sensitivity. *In muscle:* Gliclazide acts mainly by potentiating insulin action on muscle glycogen synthetase. *In the liver:* Gliclazide decreases hepatic glucose production, leading to an improvement in fasting blood glucose levels.

Hemovascular effects: Gliclazide decreases microthrombosis by two mechanisms which may be involved in complications of diabetes: - A partial inhibition of platelet aggregation and adhesion with a decrease in markers of platelet activation (beta thromboglobulin, thromboxane B₂), - A restoration of the vascular endothelium fibrinolytic activity with an increase in t-PA activity.

Antioxidant effects: The antioxidant effects of Gliclazide that were already demonstrated in clinical pharmacology which reduces plasma levels of lipid peroxides, increase in the activity of erythrocyte superoxide dismutase.

Indication

Glucozid & Glucozid MR are indicated for control of blood glucose in patients with non-insulin dependent diabetes mellitus whose hyperglycemia can not be controlled by diet & exercise alone.

Dosage and Administration

Glucozid Tablet: The daily dose of Gliclazide (**Glucozid**) may vary from 80 to 320 mg. The recommended starting dose is 160 mg daily (2 tablets/day), i.e. 1 tablet of **Glucozid** taken as twice in a day with meals. The total daily dose should not exceed 320 mg. Patients with renal or hepatic impairment may require dosage reduction.

Glucozid MR Tablet: The daily dose of Gliclazide MR (**Glucozid MR**) may vary from 30 to 120 mg once daily (i.e. 1 to 4 tablets of **Glucozid MR 30** or ½ to 2 tablets of **Glucozid MR 60**). The recommended starting dose is 30 mg daily, i.e. 1 tablet of **Glucozid MR 30** or ½ tablet of **Glucozid MR 60**, even in elderly patients over 65 years. The daily dose should not exceed 120 mg. Patients with renal or hepatic impairment should be started with **Glucozid MR 30** with dosage adjustment being made cautiously.

Contraindication

Gliclazide is contraindicated in patients with known hypersensitivity or allergy to Gliclazide, other sulfonylureas, sulfonamides or to any of the excipients of this products. It is also contraindicated in Type 1 diabetes mellitus, particularly juvenile diabetes, diabetic ketoacidosis, diabetic pre-coma & coma, serious infection, trauma or surgery, severe hepatic & renal impairment, treatment with miconazole via systemic route or oromucosal gel, pregnancy & lactation.

Warning & Precaution

Care should be exercised in patients with hepatic and renal impairment and a small starting dose should be used with careful patient monitoring. Use of Gliclazide must be considered as treatment in addition to proper dietary regimen and not as substitute for diet. Since the effects of oral hypoglycemic agents on the vascular changes and long term sequelae of diabetes mellitus are not fully known, patients receiving such drugs must be closely observed for both short and long term complications. Periodic assessment of cardiovascular, ophthalmic, renal and hepatic status is advisable. Gliclazide use is not recommended with medications containing alcohol, phenylbutazone (systemic route) and danazol and precautions are required when used with chlorpromazine, glucocorticoids, ritodrine, salbutamol, terbutaline and anticoagulant therapy.

Side Effect

Hypoglycemia may occur in concurrent conditions such as hepatic & renal diseases, alcohol intoxication, adrenal & pituitary insufficiency. Gastrointestinal disturbance including nausea, epigastric fullness, heart burn are most common but dose related and may disappear when dose is reduced. Allergic skin reactions including rash, pruritus, erythema & urticaria have been reported. These may be transient and may disappear despite continued use of the drug. If skin reactions persist, discontinue the drug.

Use in Special Group

Pregnancy: Gliclazide is contraindicated in pregnancy. **Nursing mothers:** Gliclazide should not be used during breast-feeding. **Pediatrics (<18 years of age):** Safety and effectiveness of in children have not been established. Therefore, Gliclazide is not recommended for use in children and adolescents. **Geriatrics (≥ 65 years of age):** No clinically significant modifications in the pharmacokinetic parameters have been observed in elderly patients. **Hepatic impairment:** Gliclazide is contraindicated in patients with severe hepatic impairment. **Renal impairment:** The metabolism and excretion of sulfonylureas including Gliclazide may be slowed in patients with impaired renal function. Therefore, Gliclazide is contraindicated in patients with severe renal impairment.

Drug Interaction

Sulfonamides, tuberculostatic, NSAIDs, fibrates, MAO inhibitors, salicylates, probenecid, beta-blockers, H₂ receptor antagonist, ACE inhibitors, clarithromycin may enhance the hypoglycemic effect of Gliclazide. Certain diuretics (thiazides, furosemide), corticosteroids, oral contraceptives (estrogen plus progestogen), chlorpromazine, ritodrine, salbutamol may decrease the hypoglycemic effect of Gliclazide. Barbiturates should be used with caution in patients receiving an oral hypoglycemic agent since they may reduce the hypoglycemic effect. Sulfonylureas may potentiate the action of anticoagulants. Adjustment of the anticoagulant dose may be necessary.

Overdosage

Overdosage with sulfonylureas may result in hypoglycemia but it should be noted that the dosage which causes such hypoglycemia varies widely and may be within the accepted therapeutic range in sensitive individuals. Discontinue medication and treat hypoglycemia by giving dextrose promptly and in sufficient quantity.

Storage

- Store below 30° C, keep in dry place & protect from light
- Keep out of the reach of children.

Packing

Glucozid Tablet: Each box contains 60 tablets in Alu-PVC blister pack.

Glucozid MR 30 Tablet: Each box contains 30 tablets in Alu-PVDC blister pack.

Glucozid MR 60 Tablet: Each box contains 30 tablets in Alu-PVDC blister pack.