Glyzide

Oral Antidiabetic Agent
Tablets

Composition

Each tablet contains:

Active ingredient: Gliclazide 80mg

Excipients: Lactose, cellulose, povidone, starch, magnesium stearate, and primojel.

Properties

Gliclazide, the active component of **Glyzide**, is an oral antidiabetic agent belonging to sulfonylureas. It acts by stimulating the islet tissue of the pancreas to secrete insulin and by increasing the sensitivity of peripheral tissues to insulin.

At therapeutic doses, **Glyzide** has also been shown to reduce the vascular complications caused by diabetes as it reduces platelet adhesiveness and aggregation and increases fibrinolytic activity. It also restores the prostaglandin balance by increasing prostacyclin (vasodilator and antiaggregant) and decreasing thromboxane A_2 (vasoconstrictor and proaggregant). Controlled studies suggested that gliclazide slow down the progression of retinopathy in diabetic patients.

Gliclazide is rapidly and well-absorbed from the gastrointestinal tract. Peak plasma concentrations occur 2-4 hours after administration. Gliclazide is extensively bound to plasma proteins (about 85%). The elimination half-life of gliclazide is 10-12 hours. It is extensively metabolised in the liver and all the metabolites are devoid of hypoglycaemic activity. It is mainly excreted in the urine and the rest in the faeces as metabolites.

Indications

Glyzide is indicated for non-insulin-dependent diabetes mellitus (Type II, maturity-onset diabetes) whenever dietary control and weight reduction in addition to changes in level of physical activity have proved inadequate.

Dosage

There is no fixed dosage regimen for the management of diabetes mellitus with **Glyzide**, or any other antidiabetic agent. The dose should be adjusted according to the individual patient's response, commencing with 40-80mg daily and increasing until adequate control is achieved. A single daily dose with breakfast should not exceed 160mg and when higher doses are required, a twice-daily dosage is advised and should be divided according to the main meals; 1 tablet with breakfast and 1 tablet with dinner. Maximum daily dosage should not exceed 320mg.

Notes:

- Compliance to diet and regular dosage intake are of utmost importance for successful treatment. It is very important not to skip meals after the administration of antidiabetic agents.
- If changing from other oral antidiabetic drugs (except chlorpropamide) to **Glyzide**, no transition period is required whereas transferring the patient from chlorpropamide, a consideration must be given to the potency and duration of action of this agent and a washout period of 1 to 2 weeks between drugs should be considered to avoid additive effects which would increase the risk of hypoglycaemia.

Contraindications

It should not be used in patients hypersensitive to gliclazide, other sulfonylureas, other sulfonamides, or any of the excipients.

It is contraindicated in patients with diabetes mellitus complicated by ketoacidosis as well as in those with porphyria.

Precautions

As with other sulphonylureas, gliclazide tends to encourage weight gain and should be prescribed for non-insulin-dependent (type II) diabetes mellitus only if poor control and symptom persist despite adequate attempts at dieting.

Hypoglycaemic reactions may result from overdosage with gliclazide, from interactions with certain co-administered drugs, or from dietary errors.

Gliclazide should be given cautiously in elderly as well as in patients with severe hepatic or renal impairment because of the increased risk of hypoglycaemia. Careful monitoring of blood-glucose concentration is essential; care is required to choose the smallest possible dose that produces adequate control of blood glucose.

Insulin therapy should be instituted temporarily during intercurrent illness (such as myocardial infarction, coma, infection, and trauma) and during surgery since control of diabetes with the oral antidiabetic agents is often inadequate in such circumstances.

Pregnancy: There is an increased risk of developing neonatal hypoglycaemia with the use of oral antidiabetic agent during pregnancy, particularly in the third trimester. Insulin therapy is usually substituted during pregnancy. If oral antidiabetic agent is to be administered, therapy should be stopped at least 2 days before delivery.
Lactation: As there is theoretical possibility of developing hypoglycaemia in infants, gliclazide should not be used during breast-feeding.

Side Effects

Glyzide is generally well-tolerated. Side effects are mild and infrequent and include gastrointestinal disturbances and headache.
Sensitivity reactions have been reported less frequently in the first 6 - 8 weeks of therapy. These reactions may include fever, jaundice, and transient rashes, which may rarely progress to erythema multiforme and exfoliative dermatitis.
Blood disorders are rarely reported and may include thrombocytopenia, agranulocytosis, and aplastic anemia.

Overdosage

The expected symptom of overdose will be that of hypoglycaemia. Warning symptoms are headache, irritability, profuse sweating, insomnia, tremor, and impairment of performance. Induction of emesis by gastric lavage and/or administration of syrup of ipecac should only be performed if the patient presents within the first few hours after ingestion. Hypoglycaemia is usually controlled by intake of sugar with water. The physician should be consulted immediately. Appropriate measures with continued monitoring of the patient's blood glucose until the effect of the drug has ceased. Other supportive measures should also be employed as needed.

Drug Interactions

Concurrent administration of gliclazide with the following agents enhances its hypoglycaemic effect:
Alcohol; non-steroidal anti-inflammatory agents (including phenylbutazone, azopropazone, and possibly the others); beta-blockers*; oral anticoagulants**; antibacterials (e.g., chloramphenicol, co-trimoxazole, and sulphonamides); antifungals (e.g., fluconazole and miconazole); cimetidine; ACE inhibitors; MAO inhibitors; anabolic steroids; testosterone; sulphinpyrazone.
The hypoglyceamic effect of gliclazide may be antagonised by the effect of the following agents when used concurrently:
Diuretics (e.g., loop and thiazide diuretics); diazoxide; phenothiazines; corticosteroids; oral contraceptives (oestrogen and progestogens).
As with other sulphonylureas, the metabolism of gliclazide may possibly be accelerated upon concurrent administration with rifamycins and aminoglutethimide (hormone antagonist), resutling in a reduction in its hypoglycaemic effect.
Upon concurrent administration, octreotide (hormone antagonist) may possibly reduce the requirement to antidiabetic drugs including gliclazide.
Lithium and nifedipine may occasionally impair glucose tolerance whereas clofibrate group may improve glucose tolerance and have an additive effect upon concurrent administration.

* *Beta-blockers usually mask the warning signs of hypoglycaemia such as increased heart rate or tremor.*

** *Increased anticoagulant effect of warfarin and other coumarins has also been reported upon concurrent administration.*

Presentation

Glyzide tablets: Pack of 60 tablets.

* *Store at a temperature of 15-25°C, in a dry place.*

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of the children.

**Council of Arab Health Ministers,
Union of Arab Pharmacists.**

***Any information ? Call Our Toll Free No.* (971) 800-4994**

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01/04/2000