Only for the use of medical professionals

Lozide®

Gliclazide

Presentation

Lozide® 80mg tablets are white, flat with beveled edge with cross break line, and other side plain. Each tablet contains Gliclazide BP 80mg.

Indications and uses

Gliclazide is a second generation oral hypoglycaemic agent of the sulphonylurea. Gliclazide stimulates insulin secretion by the beta-cells of pancreas. In addition, it exerts extra pancreatic effects – improves metabolic utilization of glucose at the peripheral level. Gliclazide is well absorbed and peak plasma concentrations occur 4 to 6 hours after administration. Gliclazide is 85-97% bound to plasma proteins. Metabolism is extensive and all metabolites are devoid of hypoglycemic activity. 60-70% of the dose is excreted in the urine and 10-20% in the faeces as metabolites. The elimination half-life of Gliclazide is 10 to 12 hours.

Maturity-onset stable non-insulin dependent diabetes mellitus (Type 2), when dietary management alone has failed to control hyperglycemia.

Dosage and Administration

The dosage regimen depends on the individual requirements of the patient and is at the discretion of the physician. According to the severity of the diabetic state, the dose is generally 40-80 mg daily for mild cases and up to 320 mg daily in two divided doses for severe cases, preferably with or before meals. In the majority of cases,160 mg per day with meals 80 mg with breakfast and 80 mg with dinner.

Lozide® may be used in conjunction with insulin in insulin dependent diabetes, but in that case, diabetic control should be checked by blood sugar readings, because of possibility of hypoglycemia. In combined therapy with a biguanide, there may be a greater risk of cardiovascular mortality than with the use of gliclazide alone.

Use in pregnancy and lactation

It is important to achieve strict normoglycaemia during pregnancy. Oral hypoglycaemic agents should be replaced by insulin. While studies have not shown any teratogenic effect gliclazide should only be used in women likely to become pregnant if the benefits outweigh the potential risk.

Some sulphonylureas are excreted in human breast milk. Because of the potential for hypoglycaemia in nursing infants, a decision should be made to either discontinue breastfeeding or to discontinue the medication taking into account the importance of the medication to the mother.

Children

Safety and effectiveness in children have not been established.

Side effects

Skin reactions, headache; gastrointestinal disturbances such as nausea, vomiting, diarrhea, epigastric pain; dizziness, Weakness, paraethesia; sensitivity reactions with fever, eosinophylic jaundice and skin rashes; blood disorders, including leucopenia, thrombocytopenia, aplastic anaemia and agranulocytosis.

Precautions:
Close observation and careful initiation and adjustment of dosage is mandatory in patients who are elderly, debilitated, malnourished, semi-starved or simply neglect dietary restrictions. Severe hypoglycaemia may occur in such patients requiring corrective therapy over a period of several days. Patients who have been previously treated with sulphonylureas or biguanides alone or in combination may be transferred to gliclazide. When gliclazide is administered as sole therapy to patients who have previously been receiving combination therapy careful observation is required during the transitional phase. It is not generally recommended that insulin treated patients be transferred to gliclazide.

Contra-indications:
Juvenile- onset diabetes (Type 1) and unstable or brittle diabetes diabetes complicated by acidosis, ketosis or coma. Acute complications such as severe trauma, fever, infection or surgery. Severe renal, hepatic, adrenal or thyroid dysfunction. Known hypersensitivity to sulphonylureas.

Drug Interactions
Potentiation of the hypoglycaemic action of the drug may occur with the concomitant administration of aspirin, sulphonamides, phenylbutazone, clofibrate,beta adrenoreceptors blocking agents, MAO inhibitors, coumarin anticoagulants, chloramphenicol, miconazole, cimetidine, cyclophosphamide and alcohol. Beta-blockers may mask the symptoms of hypoglycemia and may inhibit normal physiological response to hypoglycemia.
Diminution of the hypoglycemic action of the drug may occur with the concomitant administration of thiazide diuretics, corticosteroids, oestrogens, adrenaline, rifampicin and barbiturates.

Overdosage
Overdose may result in severe hypoglycemia leading to coma in some cases. Hypoglycemic reactions should be treated by the administration of intravenous glucose. The patient's blood sugar level should be continuously monitored until the effect of the drug has ceased. Hypoglycemic reactions should alert the physician to the possibilities of renal dysfunction.

Pharmaceutical Precautions
Store in a cool and dry place. Protect from light.

Package Quantities
Lozide® 80 mg Tablet: Each Carton contains 40 tablets in Alu-PVC blister.

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Narayanganj, Bangladesh