

Package Insert

DIANID TABLET



COMPOSITION :

Each tablet contains :-

Gliclazide 80 mg

DOSAGE FORM AVAILABLE :

ORAL : TABLET 80 mg

PRODUCT DESCRIPTION :

Round, flat, white tablet, having cross score on one surface.

ACTIONS :

Gliclazide is a second generation sulphonylurea oral hypoglycemic agent. It reduces blood glucose levels in healthy volunteers and patients with non-insulin dependent diabetes mellitus (NIDDM) by correcting both defective insulin secretion and peripheral insulin resistance. Unstimulated and stimulated insulin secretion from pancreatic β -cells is increased following administration of gliclazide. This occurs via the binding of gliclazide to specific receptor on pancreatic β -cells which results in a decrease in potassium efflux and causes depolarisation of the cell. Subsequently, calcium channels open, leading to an increase in intracellular calcium and induction of insulin release. In addition, gliclazide increases the sensitivity of β -cells to glucose. Gliclazide may have extrapancreatic effects which restore peripheral insulin sensitivity, such as decreasing hepatic glucose production and increasing glucose clearance and skeletal muscle glycogen synthase activity. Gliclazide is well absorbed and peak plasma concentrations occur 2-4 hours after administration. Gliclazide is 85% bound to plasma proteins. Metabolism is extensive and all the metabolites are devoid of hypoglycemic activity. 60-70% of the dose is excreted in the urine, <5% of the dose is excreted unchanged in the urine and 10-20% in the faeces as metabolites. The elimination half-life of gliclazide is 10-12 hours.

INDICATIONS :

For the treatment of Non-insulin-dependent diabetes mellitus (NIDDM).

DOSAGE AND ADMINISTRATIONS :

The usual initial dose is 40 to 80 mg daily, gradually increased, if necessary, up to 160 mg daily. A single dose should not exceed 160 mg and when higher doses are required the dosage should be divided and taken twice daily with morning and evening meals.

OVERDOSAGE - SYMPTOMS, TREATMENT, SUPPORTIVE

THERAPY, ANTIDOTE (S) :

The symptom of overdosage would be hypoglycemia. The treatment is gastric lavage and intravenous administration of hypertonic glucose.

CONTRAINDICATIONS :

DIANID should not be used alone in insulin-dependent diabetes, diabetes complicated by ketosis and acidosis, pregnancy, severe impairment of renal, hepatic or thyroid function, diabetics undergoing surgery, after severe trauma or during infections, patients known to have hypersensitivity to sulfonylureas and related drugs.

PRECAUTIONS AND WARNINGS :

To maintain control of diabetes during period of stress (e.g., trauma, fever, infection), the temporary use of insulin, either alone or in combination with gliclazide may be required. To reduce risk of hypoglycemia a number of precautions should be taken when gliclazide is first prescribed, including adjusting the dose according to blood and urinary glucose levels during the first few months, and beginning treatment with low doses in patients with renal and/or hepatic impairment. Hypoglycemia may occur if the patient's dietary intakes is reduced or after accidental or deliberate overdose.

Use in pregnancy :

Gliclazide is contraindicated in pregnancy.

Use in lactation :

Gliclazide is secreted in breast milk and patients taking gliclazide should not breast feed.

ADVERSE EFFECTS :

Gliclazide is generally well tolerated. Mild gastrointestinal and central nervous system disturbances and dermatological effects are occasionally noted. Gastrointestinal disturbances (nausea, diarrhoea, gastric pain, constipation, vomiting) with an incidence of 2 to 20% Central nervous system disturbance (light-headedness, dizziness) with an incidence of 4 to 27% Dermatological disturbance (rash, pruritus, urticaria, erythema, flushing) with an incidence of 8 to 14% Hypoglycemia with an incidence of 3.8 to 16.7% Limited animal data and clinical data have indicated that gliclazide may included adverse cardiovascular effects.

DRUG INTERACTIONS :

Potential of the hypoglycemic action of the drug may occur with the concomitant administration of sulfonamides, salicylates, phenylbutazone, β -adrenoreceptor antagonist, MAOIs, Ketoconazole and miconazole. Diminution of the hypoglycemic action of the drug may occur with the concomitant administration of thiazide diuretics, corticosteroids and oestrogens. A case report has described facial flushing and nausea within 20 minutes of drinking alcohol in a 58-year-old treated with gliclazide.

STORAGE :

Store at room temperature not exceeding 30°C. Protect from light and moisture. The shelf-life period is 5 years.

SUPPLY :

Blister pack in printing box of 10x10's, 50x10's



Manufactured by
BIOLAB CO., LTD.

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