DIAMITEX TABLET 80 MG

DESCRIPTION:
DIAMITEX TABLET 80MG : A 8 mm round tablet, white in colour with double scored at one side and plain at another side.

COMPOSITION:
DIAMITEX TABLET 80MG : Each tablet contains Gliclazide 80 mg.

PHARMACODYNAMICS:
Gliclazide stimulates insulin secretion from functional pancreatic beta-cells to a glucose stimulus. (Some residual beta-cell function is therefore necessary). Gliclazide restores the diminished first-phase of insulin secretion noted in non-insulin dependent diabetes mellitus. Any long-term hypoglycaemic activity of Gliclazide can be attributed to an ability to maintain its effects on insulin secretion. Extrapancreatic effects may also be involved in the long-term efficacy of Gliclazide. Extrapancreatic effects demonstrated for Gliclazide include improvement in insulin-mediated glucose utilisation and potentiation of post-receptor insulin sensitive pathways. At normal therapeutic doses in man, Gliclazide reduces platelet adhesiveness aggregation.

PHARMACOKINETICS:
Gliclazide is absorbed in the gastrointestinal tract reaching peak plasma concentrations within 4–6 hours. Single dose studies have demonstrated that maximal falls in blood glucose levels (23% - 80 mg dose; 30% - 160 mg dose) occur approximately 5 hours after drug administration; nine hours after a dose of 160 mg, a reduction of 20% was still in evidence. The half life of Gliclazide is approximately 12 hours.

INDICATIONS:
Diabetes mellitus of the maturity onset type, which cannot be controlled by diet alone.

RECOMMENDED DOSE:
The dosage of Gliclazide should be carefully titrated to maintain optimal control at the various possible dose levels. Dosage should be initiated at 40 mg (½ tablet) daily and may be increased if necessary to 320 mg (4 tablets daily). Doses up to 160 mg daily may be taken in a single daily dose but preferably at the same time each morning. Doses in excess of 160 mg should be taken in divided doses in the morning and evening. In general, the dosage will depend on the severity of the glycaemia with ongoing adjustments made in order to obtain the optimal response at the lowest dosage. Treatment with Gliclazide does not obviate the necessity for maintaining standard dietary regulations.
Transferring to Gliclazide: 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 (e.g. biguanides and sulphonylureas), careful observation is essential during the transitional phase. It is not generally recommended that insulin treated patients be transferred to Gliclazide.
The dose may need to be titrated if a patient has been switched from a different brand of product containing Gliclazide.

ROUTE OF ADMINISTRATION: Oral

CONTRAINDICATIONS:
Gliclazide should not be used in diabetes complicated by acidosis, ketosis or coma, or in patients with a history of repeated episodes of ketoacidosis or coma.
Juvenile onset diabetes and unstable or brittle diabetes: As sulphonylurea hypoglycaemic agents are not effective in juvenile onset, unstable or brittle diabetes, Gliclazide should not be used in these conditions.
Severe renal and liver disease: Gliclazide is contraindicated in severe hepatic or renal insufficiency. Caution should be exercised and dosage reduction may be required.
Hypersensitivity: Gliclazide should not be used in patients with known sensitivity to sulphonylureas.

WARNING & PRECAUTIONS:
Acute complications such as severe trauma, fever, infection or surgery: These acute complications provoke additional metabolic stress which accentuate the predisposition to hyperglycaemia and ketosis. Patients presenting with such conditions may require insulin to maintain control. It is not appropriate to increase the dosage of Gliclazide.
Hypoglycaemia: Close observation and careful initiation and adjustment of dosage, is mandatory in patients who are elderly, debilitated, malnourished, semi-starved or simply neglecting dietary restrictions. In such patients severe hypoglycaemia may occur and may require corrective therapy over a period of several days. Certain conditions such as alcoholism, insulinoma, adrenal thyroid and pituitary insufficiency increase the sensitivity to sulphonylureas and may dispose to hypoglycaemia.

Precautions:
Monitoring of diabetic state: As with other anti-diabetic therapies, patients must be under constant medical supervision. Particular care must be taken during the initial period of stabilisation. Patients treated with Gliclazide must be monitored regularly to ensure the optimal control of the diabetic state and where necessary, for the adjustment of dosage.
Disturbances of blood sugar control: As with all hypoglycaemics, caution should be observed in administering thiazide to patients on Gliclazide therapy, since thiazides have been reported to aggravate the diabetic state. Other drugs which may adversely affect blood sugar control with hypoglycaemic agents in some patients, include barbiturates, glucocorticoids and oestrogens.
Potentiation of hypoglycaemic effect: Certain drugs may potentiate the effect of Gliclazide and thereby increase the risk of hypoglycaemia. These include insulin, biguanides, sulphonamides, oxyphenbutazone, phenylbutazone, clofibrate, salicylates, coumarin derivatives, chloramphenicol, M.A.O. inhibitors, beta blockers and ethanol.
Alcohol: Acute alcohol intoxication potentiates the hypoglycaemic action of all sulphonylurea agents. Furthermore, ingestion of alcohol may cause a disulfiram-like reaction with characteristic flushing of the face, throbbing headache, giddiness, tachyponea, tachycardia or angina pectoris. Chronic alcohol abuse may, as a result of liver enzyme induction, stimulate the metabolism of sulphonylurea drugs and shorten plasma half-life and duration of action.

INTERACTION WITH OTHER MEDICATIONS:
As in Chlorpropamide – **DRUG INTERACTIONS:** Enhanced Effect – In 5 diabetics poorly controlled with sulphonylurea treatment, tolerance to glucose was improved when mebanazine 20 mg daily was given for 5 weeks. Since salicylic acid, phenylbutazone, ethionamide, and aminosalicylic acid lowered blood-sugar concentrations they were associated with severe hypoglycaemic reactions in patients being treated with sulphonylureas including chlorpropamide. Enhancement of the effect of phenformin with a sulphonylurea during treatment with halofenate. Two of thirteen patients taking chlorpropamide had hypoglycaemic episodes when halofenate 1 g daily was added to their treatment.

USE IN PREGNANCY & LACTATION:
Pregnancy: Gliclazide should not be used in pregnant women. Whilst, animal studies of Gliclazide have not shown any teratogenic effect, Gliclazide should only be used in women who are likely to become pregnant if the expected benefits outweigh any potential risk.
Use during lactation: Gliclazide should not be used during lactation.

SIDE EFFECTS:
Adverse reactions have occurred in some 12% of cases in clinical studies. However, approximately 2% of patients were withdrawn from therapy because of adverse reactions notably hypoglycaemia, gastro-intestinal disturbances (constipation, nausea, epigastric discomfort and heartburn), dermatological reactions (rash and transient itching), and biochemical abnormalities (elevated serum creatinine, increased serum alkaline phosphatase, raised serum SGOT, elevated BUN and raised serum bilirubin). Headache, slight disulfiram-like reactions and lassitude have also been reported. Serious reactions which have been reported with other sulphonylureas are leukopenia, thrombocytopenia, agranulocytosis, pancytopenia, haemolytic anaemia, cholestatic jaundice and gastrointestinal haemorrhage. These reactions have not been reported with Gliclazide. As in the case with all forms of antidiabetic therapy, hypoglycaemic reactions have occasionally been reported following Gliclazide administration. Severe hypoglycaemia, though very rarely reported, may occur in patients receiving Gliclazide.

SYMPTOMS AND TREATMENT OF OVERDOSE:

Clinical Features: Manifestations of severe hypoglycaemia result from overdosage. Hypoglycaemia caused by sulphonylurea agents differs in several aspects from insulin coma. Warning symptoms are often absent, neurological syndromes are frequent and coma is often prolonged.

Management – Consciousness should be restored by the administration of intravenous glucose or glucagon injection, care being taken to ensure against the return of hypoglycaemia by constant monitoring of the blood sugar level.

STORAGE CONDITIONS:

Store below 30°C. Protect from light. Keep out of reach of children. *Jauhkan daripada kanak-kanak*.

PACK SIZE:

Blister pack of 10 x 10's and 50 x 10's tablets in a box.

SHELF LIFE:

Please refer to outer package.

PRODUCT REGISTRATION HOLDER & MANUFACTURER:

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