GLICLAZIDE

AZUKON MR

30 mg Prolonged Release Tablet
Oral Hypoglycemic

xxxxxxxx-5343

FORMULATION:
Each prolonged release tablet contains:
Gliclazide..... 30 mg

PHARMACOLOGY:
Gliclazide stimulates the secretion of insulin from functioning pancreatic islet B-cells. In addition to this pancreatic action, it has been demonstrated that Gliclazide administration may improve the metabolic utilization of glucose at a peripheral level.

INDICATIONS:
For the treatment of Type II Diabetes Mellitus.

DOSAGE AND METHOD OF ADMINISTRATION:
Usual Daily Dose: 1 tablet once daily increased if necessary up to 4 tablets as a single dose preferably followed by a meal.

CONTRAINDICATIONS:
Hypersensitivity to sulfonylureas and related substances. Not to be used for: juvenile onset diabetes; diabetes complicated by ketosis or acidosis; diabetics undergoing surgery, after severe trauma or during infections; diabetic precoma and coma; severe renal or hepatic insufficiency, porphyria, hyperthyroidism, pregnancy and lactation.

WARNING:
The administration of oral hypoglycemics may be associated with increased cardiovascular mortality as compared to treatment with diet alone or diet with insulin. A reduction in dosage may be necessary in patients with renal dysfunction.

PRECAUTIONS:
Gliclazide as other sulfonylureas, is capable of producing moderate to severe hypoglycemia, particularly in the following conditions; in patients controlled by diet alone; in case of accidental overdose; when calorie or glucose intake is deficient; in patients with hepatic and/or renal impairment, however, in long-term clinical trials, patients with renal insufficiency have been treated satisfactorily, using Gliclazide at reduced doses. Dosage adjustments may be necessary, on the occurrence of mild symptoms of hypoglycemia (sweating, pallor, hunger pangs, tachycardia, and sensation of malaise). Such findings should be treated with oral glucose and adjustments made in medicine dosage and/or meal patterns; on the occurrence of severe hypoglycemic reactions (coma or neurological impairment, see overdosage), loss of control of blood glucose (hyperglycemia). When a patient stabilized on any diabetic regimen is exposed to stress such as fever, trauma, infection or surgery, a loss of control may occur. At such times it may be necessary to progressively increase the dosage of Gliclazide and if this is insufficient, discontinue the treatment of Gliclazide and to administer insulin.
Abnormalities of hepatic function may occur during Gliclazide therapy. There are less frequent reports of hepatic failure, hepatitis and jaundice following treatment with Gliclazide.
Care should be exercised in patients with hepatic and/or renal impairment and a small starting dose should be used with careful patient monitoring. As with other sulfonylureas, hypoglycemia will occur if the patient's dietary intake is reduced or if they are receiving a larger dose of Gliclazide than what is required.
Patients should be informed that their concentration might be affected if their diabetes is not satisfactorily controlled, especially at the beginning of treatment.

PREGNANCY AND LACTATION
If patient is pregnant, diabetes should be treated with insulin. Inform the doctor if the patient wishes to become pregnant. Some sulfonylureas are distributed into breast milk and the class of drugs should be avoided during breast feeding.

DRUG INTERACTIONS:
Care should be taken when using Gliclazide with medicines, which are known to alter the diabetic state or potentiate the medicines action. The hypoglycemic effect of Gliclazide may be potentiated by phenylbutazone, salicylates, sulfonamides, coumarin derivatives, monoamine oxidase inhibitors, beta-adrenergic blocking agents, tetracycline compounds, chlorampehnicol, clofibrate, disopyramide, oral forms of miconazole and cimetidine.
The hypoglycemic action of Gliclazide may be diminished by corticosteroids, oral contraceptives, thiazide diuretics, phenothiazines derivative, thyroid hormones and abuse of laxatives.

ADVERSE EFFECTS:
Gastrointestinal disturbances such as nausea, vomiting, heartburn, anorexia, diarrhea, and a metallic taste may occur and are usually mild and dose-dependent; increased appetite and weight gain may occur. Skin rashes and pruritus may occur photosensitivity has been reported. Rashes are usually hypersensitivity reactions which may progress to more serious disorders.
Mild hypoglycemia may occur; severe hypoglycemia is usually an indication of overdosage and is relatively uncommon.
Other severe effects may be manifestations of a hypersensitivity reaction. They include altered liver enzyme values, hepatitis and cholestatic janudice, leucopenia, thrombocytopenia, aplastic anemia, agranulocytosis, hemolytic anemia, erythema multiforme or the Stevens-Johnson syndrome, exfoliative dermatitis and erythema nodosum.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

STORAGE:
Store at temperatures not exceeding 30°C.

AVAILABILITY:
Alu-PVC Blister Pack of 10's, Box of 100 Prolonged Release Tablets

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Manufactured by :
TORRENT PHARMACEUTICALS LTD.
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Imported and Distributed by:
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