For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory 8042338-8883

AZUKON MR

(Gliclazide Modified Release Tablets, 30mg)

COMPOSITION
Each uncoated modified release tablet of AZUKON MR contains Gliclazide B.P. 30mg.
PROPERTIES
Gliclazide is a second-generation sulphonylurea drug, having hypoglycemic and potentially useful hemobiological action.
CLINICAL PHARMACOLOGY
PHARMACODYNAMICS
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.
PHARMACOKINETICS
Single oral dose of Gliclazide 30 mg resulted in a Tmax of 8 to 10 hrs. 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 10-12 hours.
INDICATIONS
Therapy of maturity onset Diabetes Mellitus (non-insulin- dependent or Type II), where dietary management alone has been insufficient.
CONTRAINDICATIONS
Hypersensitivity to sulphonylureas 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.

SIDE EFFECTS AND SPECIAL PRECAUTIONS
Hypoglycaemia : Gliclazide, as other sulphonylureas, is capable of producing moderate to severe hypoglycaemia, 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 hypoglycaemia (sweating, pallor, hunger pangs, tachycardia, 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 hypoglycaemic reactions (coma or neurological impairment, see overdosage), loss of control of blood glucose (hyperglycaemia). When a patient stabilised 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, to 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.
Mild gastrointestinal disturbances including nausea, dyspepsia, diarrhoea and constipation have been reported, but this type of adverse reaction can be avoided if Gliclazide is taken with a meal.
Weight changes : Most studies report no significant overall change in weight.
Skin reactions including rash, pruritus, erythema, bullous eruption, blood dyscrasia including anaemia, leucopenia, thrombocytopenia and granulocytopenia have been observed during treatment with Gliclazide. Facial flushing may develop in patients receiving sulphonylureas.
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 sulphonylureas, hypoglycaemia will occur if the patient's dietary intake is reduced or if they are receiving a larger dose of Gliclazide than is required.
Effects on Ability to Drive and Use Machines
Patients should be informed that their concentration might be affected if their diabetes is not satisfactorily controlled, especially at the beginning of treatment.
DRUG INTERACTIONS
Care should be taken when using Gliclazide with medicines, which are known to alter the diabetic state or potentiate the medicine's action. The hypoglycaemic effect of Gliclazide may be potentiated by phenylbutazone, salicylates, sulphonamides, coumarin derivatives; monoamine oxidase inhibitors, beta-adrenergic blocking agents, tetracycline compounds, chloramphenicol, clofibrate, disopyramide, oral forms of miconazole and cimetidine.
The hypoglycaemic action of Gliclazide may be diminished by corticosteroids, oral contraceptives, thiazide diuretics, phenothiazine derivatives, thyroid hormones and abuse of laxatives.

DOSAGE AND METHOD OF ADMINISTRATION
Adults: The modified release formulation allows convenient once daily dosing of 30 mg Preferably followed by a meal
Elderly: Plasma clearance of Gliclazide is not altered in the elderly and steady state plasma levels can therefore be expected to be similar to those in adults under 65 years. Clinical experience in the elderly to date shows that Gliclazide is effective and well tolerated. Care should be exercised however, when prescribing sulphonylureas in the elderly due to a possible age-related increased risk of hypoglycaemia.
Children: Gliclazide, as with other sulphonylureas, is not indicated for the treatment of juvenile onset diabetes mellitus.
SWITCHING OF AZUKON TO AZUKON MR

DOSE OF AZUKON	DOSE OF AZUKON MR
80mg once daily	30mg once daily
80mg BID	60mg once daily
160mg a.m. and 80mg p.m.	90mg once daily
160mg BID	120mg once daily

DIRECTION FOR USE
Tablet or divided halves of the tablet to be swallowed whole. Do not chew.
DRUG ABUSE AND DEPENDENCE
Gliclazide has no known potential for abuse or dependence.
OVERDOSE AND ITS TREATMENT
Hypoglycaemic reactions should be treated by gastric lavage and correction of the hypoglycaemia by the administration of intravenous glucose. The patient's blood sugar should be continuously monitored until the effect of the drug has ceased (this may take several days). Hypoglycaemic reactions should alert the physician to the possibility of renal dysfunction.
EXPIRY DATE
Do not use later than the date of expiry.
STORAGE
Store below 30^{o}C, Protected from light
KEEP ALL MEDICATIONS OUT OF REACH OF CHILDREN
PRESENTATION AND AVAILABILITY
AZUKON MR is white to off-white, oblong shaped, biconvex, uncoated tablet with breakline on one side, available in blister strip of 10 tablets.

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Manufactured by :
TORRENT PHARMACEUTICALS LTD.
Indrad-382 721, Dist. Mehsana, INDIA.