GLICLAZIDE

AZUKON MR

30 mg Prolonged-Release Tablet
Oral Hypoglycemic

xxxxxxxx-5343

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

PRODUCT DESCRIPTION
Glicazide (Azukon MR) 30 mg Prolonged-Release Tablet is a white to off-white colored, capsule shaped uncoated tablet plain on both sides.

PHARMACOLOGICAL PROPERTIES

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
Gliclazide is readily absorbed from the gastrointestinal tract. It is extensively bound to plasma proteins. The half-life is about 10 to 12 hours. Gliclazide is extensively metabolized in the liver to metabolites that have no significant hypoglycaemic activity. Metabolites and a small amount of unchanged drug are excreted in the urine.

INDICATION
For the treatment of Type II Diabetes Mellitus.

DOSAGE AND 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.
Not to be used for insulin-dependent diabetes (type 1) and for patients taking medicines to treat fungal infections.
Gliclazide is not recommended in patients presenting galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption syndrome (rare hereditary diseases).

WARNINGS AND PRECAUTIONS
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.
Gliclazide as other sulfonylureas, is capable of producing moderate to severe hypoglycemia, particularly in the following conditions; in patients controlled by diet alone; patients who are fasting, malnourished; increase in physical activity and carbohydrate intake; patients drinking alcohol in combination with skipped meals; patients suffering from particular hormone-induced disorders; 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, headache, nausea, vomiting, weariness, sleep disorders, restlessness, aggressiveness, poor concentration, reduced alertness and reaction time, depression, confusion, speech or visual disorders, tremor, dizziness, hunger pangs, tachycardia, feelings of helplessness 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), loss of control of blood glucose (hyperglycemia). Symptoms may include thirst, frequent urination, dry mouth, dry itchy skin, skin infections and reduced performance. 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.

DRIVING AND USE OF MACHINERIES
The ability to concentrate or react may be impaired if your sugar is too low or too high, hence, patients is not advisable to drive and operate machines.

PREGNANCY AND LACTATION
Gliclazide is not recommended for use during pregnancy. Inform the doctor if the patient wishes to become pregnant for suitable treatment.
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, ACE inhibitors, tetracycline compounds, chloramphenicol, clofibrate, disopyramide, oral forms of miconazole, cimetidine, oral antidiabetics, GLP-1 receptor agonists or insulin, H2-receptor antagonists, and medicines containing alcohol.
The hypoglycemic action of Gliclazide may be diminished by corticosteroids, oral contraceptives, thiazide diuretics, phenothiazines derivative, thyroid hormones and abuse of laxatives.
Warfarin should not be administered together with Gliclazide as blood clotting action may be reduced.

ADVERSE REACTIONS
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 and photosensitivity has been reported. Rashes are usually hypersensitivity reactions which may progress to more serious disorders.
Vision may also be affected at the start of treatment due to changes in blood sugar levels.
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.
"For suspected adverse drug reaction, report to FDA: www.fda.gov.ph or to TORRENT: www.torrentpharma.com".
Patient to seek medical attention immediately at the first sign of any adverse drug reaction shall appear.

OVERDOSAGE AND TREATMENT
An overdose of sulfonylureas may cause hypoglycaemia. Patient may take sugar or sugary drinks straight away, followed by a meal.
In acute poisoning with sulfonylureas, if the patient is conscious and presents within 1 hour of ingestion, the stomach should be emptied and/or activated charcoal given. Hypoglycemia should be treated with urgency. The patient should be observed over several days in case hypoglycemia recurs. Octreotide has been used in the treatment of severe refractory cases of sulfonylurea-induced hypoglycemia.

STORAGE AND CONDITION
Store at temperatures not exceeding 30°C.

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

AVAILABILITY
Gliclazide (Azukon MR) 30 mg Prolonged-Release Tablet - Alu/PVC Blister Pack of 10's (Box of 100's) - DRP-3777

DATE OF FIRST AUTHORIZATION
August 17, 2010

DATE OF FIRST REVISION
January 2018

torrent PHARMA

Manufactured by :
TORRENT PHARMACEUTICALS LTD.
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PRODUCT NAME :	AZUKON MR	**COUNTRY :** Philippines	**LOCATION :** Indrad	**Supersedes A/W No.:**			
ITEM / PACK :	Insert	**NO. OF COLORS:** 1	**REMARK :**				
DESIGN STYLE :	Front/Back	**PANTONE SHADE NOS.:**	**SUBSTRATE :**				
CODE :	xxxxxxxx-5343	Black	**Activities**	**Department**	**Name**	**Signature**	**Date**
DIMENSIONS (MM) :	150 x 180		Prepared By	**Pkg.Dev**			
ART WORK SIZE :	S/S		Reviewed By	**Pkg.Dev**			
DATE :	23-01-2018		Approved By	**Quality**			