AZUKON MR 60

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory.

Abbreviated Prescribing information for AZUKON MR 60 (**Gliclazide Modified Release Tablets 60mg**) [Please refer the complete prescribing information available at www.torrentpharma.com] **PHARMACOLOGICAL PROPERTIES**: Gliclazide reduces blood glucose levels by stimulating insulin secretion from the β-cells of the islets of Langerhans.

INDICATIONS: Therapy of maturity onset Diabetes Mellitus (noninsulin dependent or Type II), where dietary management alone has been insufficient. **DOSAGE AND ADMINISTRATION**: The recommended starting dose is 30 mg daily (half a 60 mg tablet). If blood glucose is effectively controlled, this dose may be used for maintenance treatment. If blood glucose is not adequately controlled, the dose may be increased to 60, 90 or 120 mg daily, in successive steps. The interval between each dose increment should be at least 1 month except in patients whose blood glucose has not reduced after two weeks of treatment. In such cases, the dose may be increased at the end of the second week of treatment. **CONTRAINDICATIONS**: Hypersensitivity to the active substance or to any of the excipients, hypersensitivity to other sulphonylureas or sulphonamides, severe renal or hepatic insufficiency, type 1 diabetes, diabetic pre-coma and coma, diabetic keto-acidosis and contraindicated during treatment with miconazole and lactation. **PRECAUTIONS:** This treatment should be prescribed only if the patient is likely to have a regular food intake (including breakfast). It is important to have a regular carbohydrate intake due to the increased risk of hypoglycaemia if a meal is taken late, if an inadequate amount of food is consumed or if the food is low in carbohydrate. Hypoglycaemia is more likely to occur during low-calorie diets, following prolonged or strenuous exercise, alcohol intake or if a combination of hypoglycaemic agents is being used. **DRUG INTERACTIONS**: Miconazole, phenylbutazone, alcohol, other anti-diabetic agents (insulins, acarbose, biguanides (e.g. metformin), thiazolidinediones, dipeptidyl peptidase-4 inhibitors, GLP-1 receptor agonists, beta-blockers, fluconazole, angiotensin converting enzyme inhibitors (captopril, enalapril), H2-receptor antagonists, monoamine oxidase inhibitors (MAOIS), sulphonamides, clarithromycin, non-steroidal anti-inflammatory agents, danazol, chlorpromazine, glucocorticoids, tetracosactrin, ritodrine, salbutamol, terbutaline and warfarin. **ADVERSE REACTIONS**: Headache, intense hunger, nausea, vomiting, lassitude, sleep disorders, agitation, aggression, poor concentration, reduced awareness and slowed reactions, depression, confusion, visual and speech disorders, aphasia, tremor, paresis, sensory disorders, dizziness, feeling of powerlessness, loss of self-control, delirium, convulsions, shallow respiration, bradycardia, drowsiness, loss of consciousness, sweating, clammy skin, anxiety, tachycardia, hypertension, palpitations, angina pectoris, cardiac arrhythmia, abdominal pain, nausea, vomiting, dyspepsia, diarrhoea and constipation, rash, pruritus, urticaria, angioedema, erythema, maculopapular rashes, bullous reactions (such as Stevens-Johnson syndrome and toxic epidermal necrolysis), leucopenia, thrombocytopenia, granulocytopenia, raised hepatic enzyme levels (AST, ALT, alkaline phosphatase), hepatitis, transient visual disturbances may occur, especially on initiation of treatment, due to changes in blood glucose levels, haemolytic anaemia, pancytopenia, allergic vasculitis, hyponatraemia, elevated liver enzyme levels, impairment of liver function (e.g. with cholestasis and jaundice) and hepatitis.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.
Torrent House, Off Ashram Road,

Ahmedabad-380 009, INDIA

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(Additional information is available on request)