AZUKON MR

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

Abbreviated Prescribing information for AZUKON MR [Gliclazide Modified Release Tablets] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Gliclazide is a second-generation sulphonylurea drug, having hypoglycemic and potentially useful in hemobiological action.

INDICATION: Therapy of maturity onset Diabetes Mellitus (noninsulin dependent or Type II), where dietary management alone has been insufficient.

DOSAGE AND ADMINISTRATION: The daily dose may vary from 1 to 4 tablets per day, i.e. from 30 to 120 mg taken orally in a single intake at breakfast time. It is recommended that the tablet(s) be swallowed whole. Do not chew or crush. If a dose is forgotten, there must be no increase in the dose taken the next day. Dose needs to be changed while switching from gliclazide tablets to gliclazide modified release tablets.

CONTRAINDICATION: Known hypersensitivity to gliclazide or to any of the excipients, other sulphonylureas, sulphonamides; Type 1 diabetes; diabetic pre-coma and coma, diabetic keto-acidosis; severe renal or hepatic insufficienc; Treatment with miconazole; Lactation; Concomitant use not recommended with miconazole; and danazole.

WARNINGS & PRECAUTIONS: Caution required for hypoglycaemia (including factors which may predispose this condition like malnutrition, irregular mealtimes, skipping meals, periods of fasting or dietary changes, imbalance between physical exercise and carbohydrate intake, renal insufficiency, severe hepatic insufficiency, thyroid disorders, hypopituitarism and adrenal insufficiency, fever, trauma, infection).

DRUG INTERACTIONS: Interacts with phenylbutazone, alcohol, other antidiabetic agents (insulins, acarbose, biguanides), beta-blockers, fluconazole, angiotensin converting enzyme inhibitors (captopril, enalapril), H_2-receptor antagonists, MAOIs, sulphonamides, NSAIDs; chlorpromazine, glucocorticoids, ritodrine, salbutamol, terbutaline, anti-coagulants (warfarin).

ADVERSE REACTIONS: Hypoglycemia (signs of adrenergic counter-regulation), gastrointestinal disturbances (abdominal pain, nausea, vomiting dyspepsia, diarrhoea, constipation), rash, pruritus, urticaria, erythema, maculopapular rashes, bullous reactions, anaemia, leucopenia, thrombocytopenia, granulocytopenia, raised hepatic enzyme levels (AST, ALT, alkaline phosphatase), hepatitis, Transient visual disturbances (due to blood sugar changes), erythrocytopenia, agranulocytosis, haemolytic anaemia, pancytopenia, allergic vasculitis, cholestasis, jaundice, isolated life-threatening liver failure.

MARKETED BY:

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(Additional information is available on request)