

## AZUKON-M

### For the use of a Registered Medical Practitioner

**Abbreviated Prescribing information for AZUKON-M (Gliclazide 80mg and Metformin hydrochloride 500mg Tablets)** [Please refer the complete prescribing information for details: [www.torrentpharma.com](http://www.torrentpharma.com)]

**PHARMACOLOGICAL PROPERTIES:** Gliclazide is a second-generation sulphonylurea drug having hypoglycemic and potentially useful hemobiological action. It can control glucose level throughout 24 hours. Metformin hydrochloride is an oral antidiabetic biguanide, used in management of type II diabetes.

**INDICATIONS:** Therapy of maturity onset Diabetes Mellitus (non-insulin-dependent or Type II), where dietary management alone has been insufficient.

**DOSAGE AND ADMINISTRATION:** The usual starting dose is 2 tablets per day with meals, 1 tablet with breakfast and 1 tablet with dinner. The dose can be increased according to the severity of the disease. Patients can also be titrated from 1 tablet twice a day to 2 tablets twice a day after 2 weeks.

**CONTRAINDICATIONS:** Hypersensitivity to sulphonylureas and biguanides. 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. Metformin should be avoided in renal disease or renal dysfunction (e.g., as suggested by serum creatinine levels 1.5 mg/dL [males], 1.4 mg/dL [females] or abnormal creatinine clearance) which may also result from conditions such as cardiovascular collapse (shock), acute myocardial infarction, and septicemia.

**WARNINGS & PRECAUTIONS:** Increased cardiovascular mortality, lactic acidosis, metabolic complication which can occur due to metformin accumulation which leads to impairment of renal function and it is fatal in 50% of the cases. Exercise caution while using concomitant medications that may affect renal function or metformin disposition. Impairment of hepatic function, cardiovascular collapse (shock), acute congestive heart failure, acute myocardial infarction, interference with B<sub>12</sub> absorption, hypoglycemia and temporarily suspend the therapy for any surgical procedure. Alcohol potentiate the effect of metformin on lactate metabolism.

**DRUG INTERACTIONS:** **Gliclazide:** Interacts with phenylbutazone, salicylates, sulphonamides, coumarin derivatives, monoamine oxidase inhibitors, betaadrenergic blocking agents, tetracycline compounds, chloramphenicol, clofibrate, disopyramide, oral forms of miconazole, cimetidine, corticosteroids, oral contraceptives, thiazide diuretics, phenothiazine derivatives, thyroid hormones and abuse of laxatives. **Metformin:** interacts with ranitidine and other cationic drugs (viz. amiloride, digoxin, morphine, procainamide, quinidine, quinine, triamterene, trimethoprim, or vancomycin), nifedipine, furosemide, thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blocking drugs and isoniazid.

**ADVERSE REACTIONS:** **Gliclazide:** Hypoglycaemia (sweating, pallor, hunger pangs, tachycardia, sensation of malaise), mild gastrointestinal disturbances including nausea, dyspepsia, diarrhea and constipation, weight changes, rash, pruritus, erythema, bullous eruption, blood dyscrasia including anaemia, leucopenia, thrombocytopenia and granulocytopenia and abnormalities of hepatic function. **Metformin:** Lactic acidosis, hypothermia, hypotension, and resistant bradyarrhythmias with more marked acidosis.

**MARKETED BY:**



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(Additional information is available on request)