

## AZUKON

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

Abbreviated Prescribing information for AZUKON [Gliclazide-80mg uncoated tablets] [Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

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

**INDICATION:** In the treatment of all types of maturity onset diabetes, diabetes with or without obesity in adults, elderly, diabetes with vascular complications associated in the treatment with insulin and in insulin dependent diabetes.

**DOSAGE AND ADMINISTRATION:** Adults: The final dosage regimen depends on the individual requirements of the patient and is at the direction of the physician. According to the severity of the diabetic state, the dose will generally be between 1 tablet (80 mg) for mild cases and 4 tablets (320 mg) daily for severe cases, taken in two divided doses preferably with meals. In the majority of cases: 2 tablets per day with meals, 1 tablet with breakfast and 1 tablet with dinner. 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. 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.

**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 insufficiency; 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 or surgical intervention); Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine; G6PD-deficiency.

**DRUG INTERACTIONS:** Interacts with phenylbutazone, alcohol, other antidiabetic agents (insulins, acarbose, biguanides), beta-blockers, fluconazole, angiotensin converting enzyme inhibitors (captopril, enalapril), H<sub>2</sub>-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

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(Additional information is available on request)