



SPMC

**GLICLAZIDE TABLETS BP 80 mg**

**GLICLAZIDE TABLETS BP 40 mg**

**PRESENTATION:**

**Gliclazide Tablets BP 80mg**

Packs Sizes 500'S tablets bulk & 200'S Tablets blister.

Each White circular, flat bevelled tablets of 8.0 mm diameter with "SPC" or "SPMC" letters on one side and score mark on the reverse contains 80mg of Gliclazide.

**Gliclazide Tablets BP 40mg:**

Packs of 500 tablets or 1000 tablets

Each white circular, flat bevelled edged tablet of 7.0mm diameter with "SPC", "SPMC" or "DHS" letters on one side and score mark on the reverse contains Gliclazide BP 40mg.

**INDICATIONS AND DOSE**

Type 2 diabetes mellitus

*BY MOUTH USING IMMEDIATE-RELEASE MEDICINES*

Adult: Initially 40–80 mg daily, adjusted according to response, increased if necessary up to 160 mg once daily, dose to be taken with breakfast, doses higher than 160 mg to be given in divided doses; maximum 320 mg per day

**CONTRA-INDICATIONS**

Hypersensitivity to gliclazide, other sulfonylureas or sulfonamides, **Type I diabetes**, Diabetic pre-coma and coma, Diabetes complicated by ketosis or acidosis, Diabetics undergoing surgery, after severe trauma or during infections, Severe renal or hepatic insufficiency: in these cases, the use of insulin is recommended, Treatment with miconazole Gliclazide should, where possible, be avoided in porphyria.

**PREGNANCY:**

The use of sulfonylureas in pregnancy should generally be avoided because of the risk of neonatal

**BREAST FEEDING:**

void—theoretical possibility of hypoglycaemia in the infant. Probably too small to be harmful.

**RENAL IMPAIRMENT:**

If necessary, gliclazide which is principally metabolised in the liver, can be used in renal impairment but careful monitoring of blood-glucose concentration is essential.

**CAUTION:**

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. Clinical experience in the elderly to date shows that gliclazide is effective and well tolerated. Care should be exercised however, when prescribing sulfonylureas in the elderly due to a possible age-related increased risk of hypoglycaemia.

**SPECIAL PRECAUTIONS:**

Patient with risk factors of hypoglycaemia (e.g. malnourished, poorly compensated endocrine disorders, severe vascular disease), and with poor carbohydrate intake or imbalanced diet, stress-related states (e.g. trauma, infection, surgery), G6PD-deficiency. Mild to moderate hepatic and renal impairment.

**FOOD INTERACTION:**

May lead to onset of hypoglycaemic coma or increase of hypoglycaemic effect, and disulfiram-like reaction with alcohol. Decreased serum concentration with St. John's Wort.

**SIDE EFFECTS:**

Anaemia. angioedema. dyspepsia. gastrointestinal disorder. hypersensitivity vasculitis. hyponatraemia. severe cutaneous adverse reactions (SCARs). skin reactions

**DRUG INTERACTIONS:**

Increased hypoglycaemic effect with phenylbutazone. May decrease metabolism with chloramphenicol. May enhance effect of anticoagulant agents (e.g. warfarin).

May enhance hypoglycaemic effect with other antidiabetic agents (e.g. insulin, metformin, glucagon-like peptide-1 receptor agonists, acarbose, thiazolidinediones, dipeptidyl peptidase-4 inhibitors),  $\beta$ -blockers, fluconazole, salicylates, ACE inhibitors (e.g. captopril, enalapril), H<sub>2</sub>-receptor blockers, MAOIs, sulfonamides, quinolone antibiotics, clarithromycin, and other NSAIDs. Increased blood glucose levels with chlorpromazine (at high doses),  $\beta$ -agonists (e.g. salbutamol, ritodrine), tetracosactrin, glucocorticoids (with possible ketosis), and danazol. **Potentially Fatal:** Increased hypoglycaemic effect and possible onset of hypoglycaemia, or coma with miconazole.

**OVERDOSAGE:**

Symptoms: Hypoglycaemic reactions with or without coma, convulsions or other neurological disorders. Management: Consider carbohydrate intake, or modification of diet and dose adjustment. Administration of rapid IV injection of 50 mL (20-30%) concentrated glucose solution, followed by continuous infusion of 10% diluted glucose solution. Close monitoring is recommended.

**PATIENT COUNSELLING:**

this medicine may cause dizziness, drowsiness or loss of consciousness which may indicate a severe fall of blood sugar, if affected, do not drive or operate machinery. Adhere strictly to diabetic diet. Avoid severe or prolonged exercise.

**STORAGE:**

Keep a cool & dry place. Store below 30°C in the original package in order to protect from moisture & Light. Keep all medicines away from children.

*Manufactured by:*  
**State Pharmaceutical Manufacturing Corporation**  
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