



Gliclazide

30/80 MG



Each tablet contains:
Gliclazide.....30 mg

Each tablet contains:
Gliclazide.....80 mg



COMPOSITION :

Gliclazide MR 30 mg
Gliclazide MR 80 mg

USE:

Management of type 2 diabetes mellitus.

PREGNANCY IMPLICATIONS:

Clinical effects on the fetus: Crosses the placenta. Hypoglycemia; ear defects reported with sulfonylureas; other malformations reported but may have been secondary to poor maternal glucose control/diabetes. Insulin is the drug of choice for the control of diabetes mellitus during pregnancy.

LACTATION:

Excretion in breast milk unknown/contraindicated



CONTRAINDICATIONS :

Hypersensitivity to gliclazide, sulfonylureas, or any component of the formulation; type 1 diabetes mellitus (insulin dependent, IDDM), diabetic ketoacidosis with or without coma; renal or hepatic impairment; pregnancy (per manufacturer); breast-feeding



WARNINGS/PRECAUTIONS :

All sulfonylurea drugs are capable of producing severe hypoglycemia. Hypoglycemia is more likely to occur when caloric intake is deficient, after severe or prolonged exercise, when ethanol is ingested, or when more than one glucose-lowering drug is used. Hypoglycemia is also more likely in elderly patients, or in impaired renal or hepatic function.

Chemical similarities are present among sulfonamides, sulfonylureas, carbonic anhydrase inhibitors, thiazides, and loop diuretics (except ethacrynic acid). Use in patients with sulfonamide allergy is specifically contraindicated in product labeling, however, a risk of cross-reaction exists in patients with allergy to any of these compounds; avoid use when previous reaction has been severe. Safety and efficacy have not been established in pediatric patients.

Product labeling of sulfonylureas (in U.S.) states oral hypoglycemic drugs may be associated with an increased cardiovascular mortality as compared to treatment with diet alone or diet plus insulin. Data to support this association are limited, and several studies, including a large prospective trial (UKPDS), have not supported an association.



ADVERSE REACTIONS :

Frequency not defined.
Central nervous system: Headache, nervousness, dizziness

Dermatologic: Rash, erythema, pruritus, urticaria. Sulfonylureas have also been associated with rare photosensitivity and porphyria cutanea tarda

Endocrine & metabolic: Hypoglycemia (dose dependent), hyponatremia (rare)

Gastrointestinal: Nausea, vomiting, diarrhea, epigastric fullness, gastritis

Hematologic: Agranulocytosis, leukopenia, thrombocytopenia, anemia

Hepatic: Jaundice, LDH increased, transaminases increased

Miscellaneous: Disulfiram reaction (very low potential)





OVERDOSAGE / TOXICOLOGY :

Symptoms of overdose include severe hypoglycemia, seizures, cerebral damage, tingling of lips and tongue, nausea, yawning, confusion, agitation, tachycardia, sweating, convulsions, stupor, and coma. Intoxication with sulfonylureas can cause hypoglycemia and is best managed with glucose administration (oral for milder hypoglycemia or by injection in more severe forms).



DRUG INTERACTIONS :

ACE inhibitors: May increase the hypoglycemic effect of gliclazide; monitor

Anabolic steroids: May increase hypoglycemic effect of gliclazide; monitor

Beta-blockers: Decrease hypoglycemic effect, mask most hypoglycemic symptoms, decrease glycogenolysis; avoid use in diabetics with frequent hypoglycemic episodes.

Corticosteroids: May cause hyperglycemia; adjustment of hypoglycemic agent may be necessary.

Cyclosporine: Gliclazide may increase serum concentrations of cyclosporine.

Fluoroquinolones: A possible interaction between sulfonylureas and fluoroquinolone antibiotics has been reported resulting in a potentiation of hypoglycemic action of sulfonylureas.

H2 antagonists, antacids, oral sodium bicarbonate: May increase the hypoglycemic effect; monitor glucose response.

Rifampin: May increase metabolism of gliclazide, decreasing its effects.

Salicylates: May increase hypoglycemic effect of gliclazide.

Sulfonamides: May increase hypoglycemic effect of gliclazide.

Thiazide diuretics: Hypoglycemic effect of gliclazide may be decreased by thiazide diuretics.

Warfarin: Anticoagulant effects may be increased by sulfonylureas.

Ethanol/Nutrition/Herb Interactions:

Ethanol: Avoid ethanol (may cause hypoglycemia and/or rare disulfiram reactions).

Herb/Nutraceutical: Avoid chromium, garlic, gymnema (may cause hypoglycemia).

Stability:

Store at 20°C to 30°C (68°F to 86°F).

Mechanism of Action:

Stimulates insulin release from the pancreatic beta cells; reduces glucose output from the liver; lowers plasma glucose concentrations. Gliclazide has also been shown to decrease platelet aggregation at therapeutic doses.



PHARMACODYNAMICS / KINETICS :

Absorption: Rapid

Protein binding: 94%

Metabolism: Hepatic, to inactive metabolites

Half-life elimination: 10 hours

Time to peak: 4-6 hours





Excretion: Urine (60% to 70%) and feces (10% to 20%) as metabolites

Dosage:

Oral: Adults:

Immediate release tablet: Initial: 80-160 mg/day; typical dose range 80-320 mg/day; dosage of 160 mg should be divided into 2 equal parts for twice-daily administration; maximum dose: 320 mg/day; should be taken with meals

Sustained release tablet: 30-120 mg once daily



NOTE: There is no fixed dosage regimen for the management of diabetes mellitus with gliclazide or any other hypoglycemic agent. Dose must be individualized based on frequent determinations of blood glucose during dose titration and throughout maintenance.

Dosage adjustment in renal/hepatic impairment: Contraindicated in severe impairment

Administration:

Patients who are anorexic or NPO, may need to have their dose held to avoid hypoglycemia. Should be administered with meals.





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According to the Indian Trade Mark the company owns about 450 brands and 4600 generic manufacturing permissions in India. According to the export data analysis the company was the largest exporter of generic medicines to the Europe and Middle East

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The company medicines are present in France, Georgia, Egypt and CIF countries.



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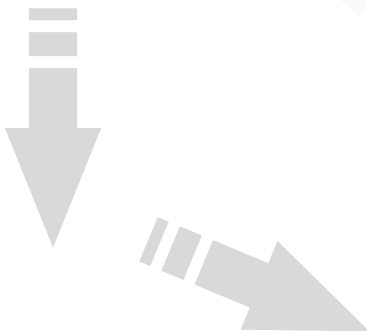
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