

Gluzit[®]

Gliclazide 80 mg Tablet

Composition

Gluzit[®] tablet: Each tablet contains 80 mg Gliclazide BP.

Description

Gliclazide is a second generation sulfonylurea that has hypoglycemic and potentially useful haemobiological properties.

Indications

Non-insulin dependent diabetes mellitus (type-II) when dietary modification has failed.

Dosage and Administrations

Dosage should be initiated at 40 mg (half tablet) daily and may be increased if necessary up to 320 mg (4 tablets) daily. Doses up to 160 mg daily may be taken in a single dose but preferably at the same time each morning. Doses in excess of 160 mg should be taken in divided doses in the morning and evening.

Side Effects

Adverse reactions, notably hypoglycemia, gastrointestinal disturbances (constipation, nausea, epigastric discomfort and heartburn), dermatological reactions (rash and transient itching), and biochemical abnormalities (elevated serum creatinine, increased serum alkaline phosphatase, raised serum AST, elevated BUN and raised serum bilirubin) were observed. Headache, slight disulfiram-like reactions and lassitude have also been reported.

Contraindications

Gliclazide should not be used in diabetes complicated by acidosis, ketosis or coma, or in patients with a history of repeated episodes of ketoacidosis or coma.

Precautions

Close observation and careful initiation and adjustment of dosage are mandatory in patients who are elderly and debilitated, malnourished, semi starved or simply neglecting dietary restrictions. In such patient, severe hypoglycemia may occur with all sulfonylureas and may require corrective therapy over a period of several days. Certain conditions such as alcoholism, insulinoma, adrenal thyroid and pituitary insufficiency increase the sensitivity to sulfonylureas and may dispose to

Use in pregnancy: Gliclazide should not be used in pregnant women. Gliclazide should only be used in women who are likely to become pregnant if the benefits outweigh the potential risk. *Use in lactation:* Gliclazide should not be used during lactation.

Drug Interactions

As with all hypoglycemics, caution should be observed in administering thiazide diuretics to patients on Gliclazide therapy, since thiazides have been reported to aggravate the diabetic state. Certain drugs may potentiate the effect of Gliclazide and thereby increase the risk of hypoglycemia. These include Insulin, Biguanides, Sulfonamides, Oxyphenbutazone, Phenylbutazone, Clofibrate, Salicylates, Coumarin derivatives, Chloramphenicol, MAOIs, β -blockers, Cimetidine and Ethanol.

Overdosage

Deliberate overdosage are likely to induce severe hypoglycemia. This may need to be treated by an intravenous infusion of 5% glucose continued for 12 to 14 h with frequent monitoring of the blood glucose level.

Pharmaceutical Precautions

Store in a cool dry place protected from light. Keep out of reach of children.

Commercial Pack

Gluzit[®] tablet: Box containing 5 X 10 tablets in blister pack.

Manufactured by :



POPULAR PHARMACEUTICALS LTD.
TONGI, GAZIPUR, BANGLADESH