

Glicron®

(Gliclazide Teblets BP)

PRESENTATION :

Glicron Tablets : white, circular, double scored tablet contains Gliclazide BP 80mg

USES :

Indication : Glicron is recommended in adults for non-insulin-dependent diabetes (type II), in association with dietary measures and with physical exercise, when these measures alone are not sufficient to obtain normal blood glucose levels.

Mode of action: Glicron (gliclazide) is a second-generation hypoglycemic sulfonylurea.

Gliclazide stimulates insulin secretion by the beta cells of pancreas. In addition, it exerts extra pancreatic effects - improves metabolic utilization of glucose at a peripheral level.

In man, apart from having a similar hypoglycemic effect to the other sulfonylureas, gliclazide has been shown to reduce platelet adhesiveness and aggregation and increase fibrinolytic activity. These factors are thought to be implicated in the pathogenesis of long-term complications of diabetes mellitus.

The drug is well absorbed and its half-life in man is approximately 10 - 12 hours. Gliclazide is metabolized in the liver; less than 5% of the dose is excreted unchanged in the urine.

DOSAGE AND ADMINISTRATION :

Adult: The total dose may vary from 40 to 320 mg/day taken orally. The dose should be adjusted according to the individual patient's response commencing with 40-80 mg daily and increasing until adequate control is achieved. A single dose should not exceed 160mg (2 tablets). When higher doses are required, Glicron should be taken twice daily and according to the main meals of the day.

Elderly: Plasma clearance of gliclazide is not altered in the elderly and steady state plasma level can therefore be expected to be similar to those in adults less than 65 years. Clinical experience in the elderly to date shows that gliclazide is effective and well tolerated.

Children: Glicron, as with other sulfonylureas, is not indicated for the treatment of juvenile onset diabetes mellitus.

CONTRAINDICATIONS :

Gliclazide should not be used in:

Juvenile onset of diabetes, Diabetes complicated by ketosis and acidosis. Pregnancy. Diabetes undergoing surgery, after severe trauma or during infections. Patients known to have hypersensitivity to other sulfonylureas and related drugs, Diabetes pre-coma and coma. Severe renal and hepatic insufficiency.

WARNINGS AND PRECAUTIONS :

Care should be exercised in patients with hepatic and/or renal impairment and a small starting dose should be used with careful patient monitoring. As with other sulfonylureas, hypoglycemia will occur if the patients' dietary intake is reduced or if they are receiving a larger dose of gliclazide than required.

DRUG INTERACTION :

Care should be taken when giving Glicron with drugs, which are known to alter the diabetic state or potentiate the drug's action. The hypoglycemic effect of Glicron may be potentiated by phenylbutazone, salicylates, sulphonamides, coumarin derivatives, MAOIs, beta-adrenergic blocking agents, tetracycline compounds, chloramphenicol, clofibrate, disopyramide, miconazole (oral forms) and cimetidine. Corticosteroids, oral contraceptives, thiazide diuretics, phenothiazine derivatives, thyroid hormones and abuse of laxatives may diminish it.

USE IN PREGNANCY AND LACTATION :

Pregnancy: Gliclazide should not be used in pregnancy.

Nursing mothers: It has not been established whether Gliclazide is excreted in human milk. However, other sulfonylureas have found in breast milk and there is no evidence to suggest that Gliclazide differs from the group in this respect.

ADVERSE REACTIONS :

All sulfonylureas are capable of producing moderate to severe hypoglycemia particularly in the conditions, when patients are controlled by diet alone; in cases of accidental overdose; when calorie or glucose intake is deficient; in patients with hepatic and/or renal impairment.

Mild gastro-intestinal disturbances including nausea, dyspepsia, diarrhoea and constipation have been reported, but this type of adverse reaction can be avoided if Glicron is taken during a meal.

Skin reactions including rash, pruritis, erythema, bullous eruption; blood dyscrasia including anaemia, leucopenia, thrombocytopenia and granulocytopenia have been observed during treatment with Gliclazide but are not known to be directly attributable to the drug.

OVER DOSAGE :


The symptom to be expected with an overdose would be hypoglycemia. The treatment is gastric lavage and correction of the hypoglycemia by appropriate means with continued monitoring of the patient's blood sugar until the effect of the drug has ceased.

PHARMACEUTICAL PRECAUTION :

Store in a cool dry place (below 30°C), away from light and children.

PACKAGE QUANTITIES :

Blister pack containing 3x10 tablets

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RENATA LIMITED
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