Glicasil®

Gliclazide 80 mg

Composition: Each tablet contains gliclazide BP 80 mg

Description: Gliclazide is a hypoglycaemic sulphonylurea differing from other related compounds by the addition of an azabicyclo-octane ring. In man, apart from having similar hypoglycaemic effect to the other sulphonylureas, 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. Gliclazide primarily enhances the first phase of insulin secretion, but also to a lesser degree its second phase. Both phases are diminished in non-insulin dependent diabetes mellitus.

Therapeutic indications: Non insulin dependent diabetes mellitus.

Dosages:
Adults: The total daily dose may vary from 40 to 320 mg taken orally. The dose should be adjusted according to the individual patient's response, commencing with 40-80 mg daily (1/2 - 1 tablet) and increasing until adequate control is achieved. A single dose should not exceed 160 mg (2 tablets). When higher doses are required, **Glicasil®** should be taken twice daily and according to the main meals of the day. In obese patients or those not showing adequate response to **Glicasil®** alone, additional therapy may be required.
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 **Glicasil®** is effective and well tolerated. Care should be exercised, however, when prescribing sulphonylureas in the elderly due to a possible age-related increased risk of hypoglycaemia.
Children: **Glicasil®** as with other sulphonylureas, is not indicated for the treatment of juvenile onset diabetes mellitus.

Contraindications: Glicasil® should not be used in Juvenile onset diabetes, diabetes complicated by ketosis and acidosis, pregnancy, diabetics undergoing surgery, after severe trauma or during infections, patients known to have hypersensitivity to other sulphonylureas and related drugs, diabetic pre-coma and coma, severe renal or hepatic insufficiency. **Special warnings and precautions for use: Hypoglycaemia:** all sulphonylureadrugs are capable of producing moderate or severe hypoglycaemia, particularly in the following conditions: in patients controlled by diet alone, in cases of accidental overdose, when calorie or glucose intake is deficient, in patients with hepatic and/or renal impairment; however, in long-term clinical trials, patients with renal insufficiency have been treated satisfactorily, using **Glicasil®** at reduced doses. In order to reduce the risk of hypo glycaemia it is therefore recommended: - to initiate treatment for non-insulin dependent diabetics by diet alone, if this is possible, - to take into account the age of the patient: blood sugar levels not strictly controlled by diet alone might be acceptable in the elderly, - to adjust the dose of **Glicasil®** according to the blood glucose response and to the 24 hour urinary glucose during the first days of treatment. Dosage adjustments may be necessary on the occurrence of mild symptoms of hypo glycaemia (sweating, pallor, hunger pangs, tachycardia, sensation of malaise). Such findings should be treated with oral glucose and adjustments made in drug dosage and/or meal patterns, on the occurrence of severe hypoglycaemic reactions (coma or neurological impairment), loss of control of blood glucose (hyperglycaemia). When a patient stabilised on any diabetic regimen is exposed to stress such as fever, trauma, infection or surgery, a loss of control may occur. At such times, it may be necessary to increase progressively the dosage of **Glicasil®** and if this is insufficient, to discontinue the treatment with **Glicasil®** and to administer insulin. As with other sulphonylureas, hypoglycaemia will occur if the patients' dietary intake is reduced or if they are receiving a larger dose of **Glicasil®** than required. Care should be exercised in patients with hepatic and/or renal impairment and a small starting dose should be used with careful patient monitoring.

Drug interaction: Care should be taken when giving **Glicasil®** with drugs which are known to alter the diabetic state or potentiate the drug's action. The hypoglycaemic effect of **Glicasil®** may be potentiated by phenylbutazone, salicylates, sulphonamides, coumarin derivatives, MAOIs, beta adrenergic blocking agents, tetracycline compounds, chloramphenicol,. clofibrate, disopyramide, miconazole (oral forms) and cimetidine. It may be diminished by corticosteroids, oral contraceptives, thiazide diuretics, phenothiazine derivatives, thyroid hormones and abuse of laxatives.

Pregnancy and lactation: ***Pregnancy:*** See "Contra-indications". Lactation: It has not been established whether gliclazide is transferred to human milk. However, other sulphonylureas have been found in milk and there is no evidence to suggest that gliclazide differs from the group in this respect.

Side-effects: - Hypoglycaemia (see special warnings and precautions). Abnormalities of hepatic function are not uncommon during **Glicasil®** therapy. There are rare reports of hepatic failure, hepatitis and jaundice following treatment with **Glicasil®**. Mild gastro-intestinal disturbances including nausea, dyspepsia, diarrhoea, constipation have been reported but this type of adverse reaction can be avoided if **Glicasil®** is taken during a meal, Skin reactions including rash, pruritus, erythema, bullous eruption; blood dyscrasia including anaemia, leukopenia, thrombocytopenia and granulocytopenia have been observed during treatment with **Glicasil®** but are not known to be directly attributable to the drug.

Storage :
Store in a cool & dry place, away from light. Keep out of the reach of children.

Commercial pack: Box containing 5 X 10 tablet in blister pack.

Manufactured by :
Silva
Pharmaceuticals Limited
Maijdee, Noakhali, Bangladesh