

Hypoglycemic

COMPOSITION

Each tablet contains: N[4-(B-(2-methoxy-5-chlorobenzamide) ethyl) benzosulfonyl]-N'-cyclohexylurea (glibenclamide) 5 mg.

PROPERTIES

GLIBORAL is an oral antidiabetic agent with intense hypoglycemic effect that persist long enough for a single daily dose to be sufficient in many cases.

In some forms of diabetes GLIBORAL normalizes the altered metabolic status.

Treatment with GLIBORAL, its use in place of other antidiabetics and in place of insulin or its use in combination with insulin is a matter for medical prescription.

INDICATIONS

Non juvenile non acidotic diabetes mellitus in over-weight sthenic subjects.

INSTRUCTIONS FOR USE AND DOSAGE

It is essential to keep strictly to the physician's instructions regarding dose, time of administration and diet.

Treatment should be under constant medical supervision. The dose of GLIBORAL must be established according to the individual's metabolic status. It is usual to start with 1/2 tablet daily (2.5 mg). Only on medical advice may the daily dose be gradually increased by 1/2 tablet at a time. Daily doses exceeding 3 tablets do not usually heighten the effect.

When GLIBORAL is used in place of other oral antidiabetics with the same type of action, it is important to know the dose previously taken and the patient's metabolic status, bearing in mind that the effect of 5 mg of GLIBORAL (1 tablet) corresponds to that of 1 g of tolbutamide, for example.

When replacing tolbutamide at doses exceeding 2 g, it is advisable to start with 10 mg of GLIBORAL (2 tablets). As a rule daily doses of up to 2 tablets can be taken in one go during the midday meal.

The quantity exceeding that dose should be taken during the evening meal.

The tablets may be swallowed whole with a little water.

CONTRAINDICATIONS

Sulfonylureas are contraindicated in insulin-dependent diabetes, ketotic diabetes, latent or suspect diabetes, in diabetic coma or precoma, in prediabetic states, in pregnancy, in severely impaired kidney or liver function and in adrenal insufficiency.

SIDE EFFECTS

Hypoglycemic reactions may occur, though rarely, in the course of treatment with sulfonylureas, chiefly in debilitated or aged individuals, in the case of unaccustomed physical effort, irregular eating habits or drinking alcoholic liquor, impaired kidney and/or liver function (see warnings).

Gastrointestinal disturbances (such as nausea, sense of epigastric fullness) and headache are very rare: they are dose-dependent and as a rule disappear when the dose is reduced, if this is compatible with metabolic control.

Allergic skin reactions have occasionally been reported, but they are transient and usually disappear as treatment goes on.

Modifications of the hemopoietic system are very rare and as a rule, reversible.

WARNINGS

The use of oral hypoglycemics of the sulfonylurea group must be confined to patients with symptomatic non ketogenic maturity-onset diabetes unresponsive to dietary management, in whom insulin is contraindicated.

In the case of hypoglycemic reactions (see side effects) give carbohydrates; in more serious reactions, which rarely reach the point of loss of consciousness, slow intravenous infusion of glucose solutions is required.

In the event of injury, surgery, infectious diseases or fever, temporary insulin therapy may be called for in order to ensure adequate metabolic control.

Patients taking sulfonylureas should be aware of the risk of disulfiram-like reactions after drinking alcohol.

The hypoglycemic action of sulfonylureas may be potentiated by dicoumarol and its derivatives, monoamine oxidase inhibitors, sulfonamides, phenylbutazone and its derivatives, chloramphenicol, cyclophosphamide, probenecid, pheniramidol and salicylates. It may, on the other hand, be weakened by adrenalin, corticosteroids, oral contraceptives and thiazide diuretics.

Care must be exercised when administering beta blockers contemporaneously.

Patients must be trained to recognize the first symptoms of hypoglycemia (usually: headache, irritability and nervous depression, sleep disturbances, tremor, profuse sweating) so that they may warn the doctor immediately. He should also be informed of intercurrent fever or digestive disorders.

KEEP OUT OF CHILDREN'S REACH

PACKING

Box of thirty 5-mg tablets.