DYANIL TABLET 5MG

MAL19910070AZ

DESCRIPTION:
TABLET
Colour : White
Shape : Oblong, Flat and Scored

EACH TABLET CONTAINS:
Glibenclamide ..... 5 mg

PHARMACODYNAMICS:
Glibenclamide is a hypoglycaemic agent which is effective when given by mouth. It acts by stimulating the release of insulin from the beta cells of the pancreatic islets. It is not a substitute for insulin as it is effective only in the presence of functioning islet tissue.

PHARMACOKINETICS:
About 45% of a 5 mg dose is absorbed after oral administration. After an oral dose of 5 mg, peak serum concentrations of about 0.04 mcg/ml are attained in 2 to 4 hours. Plasma half-life is 3 to 7 hours; half-life determined from urinary excretion data is about 10 hours. It is widely distributed throughout the body and does not appear to accumulate. About 98% is bound to plasma proteins. It is metabolised by hydroxylation of the cyclohexyl ring at positions 3 and 4; in the rat, rabbit and dog, the 3-cis-hydroxy metabolite is additionally produced; hydroxylated metabolites may be conjugated. In 5 days, 95% of a dose is excreted in the urine and faeces with about 54% excreted as unchanged drug; of the 95% excreted about 75% is found in the faeces and 20% in the urine; excretion of an intravenous dose is more rapid than that from either oral or intramuscular doses.

INDICATION:
Non-insulin-dependent diabetes mellitus (type II, maturity-onset diabetes) whenever dietary treatment alone proves inadequate.

RECOMMENDED DOSE:
Stabilisation should be instituted by a doctor only.
The tablets are to be swallowed whole with some liquid.
Treatment is started with a daily dose of half a tablet (2.5 mg), taken immediately before breakfast. If necessary, raise the dose in increments of 2.5 mg until the blood glucose levels have been normalised. As a rule, the maximum effect is obtained with 3 tablets daily, in exceptional cases 4 tablets daily. A maximum single dose of 2 tablets (10 mg) should not be exceeded. It is to be taken before breakfast, any remaining portion before the evening meal.

CONTRAINDICATION:
Insulin-dependent diabetes mellitus (type I, growth-onset diabetes), diabetic coma, diabetic metabolic decompensation (e.g. ketoacidosis), severe renal impairment, hypersensitivity to Glibenclamide, pregnancy. If children are wanted, the matter should be discussed with the doctor.

WARNING AND PRECAUTIONS:
Compliance to diet and regular tablet intake are of utmost importance for successful treatment and will prevent undesirable changes in blood sugar levels. Hypoglycaemic reactions may result from overdose of Glibenclamide, from interactions with certain drugs, or from dietary errors (e.g. omission of meals). Warning signs are headache, irritability, restlessness, profuse sweating, insomnia, tremor, impairment of performance and alertness. Such hypoglycaemic episodes are nearly always promptly relieved by the intake of sugar.
Their occurrence must be reported to the doctor without delay. The treatment of diabetes requires regular check-up. Until optimal control is achieved, or when changing the antidiabetic preparation, or when the tablets are not taken regularly, the patient’s alertness and reactivity may be impaired to such an extent as to make him unable to cope with road traffic or operate machinery. When situations of unusual stress arise (e.g. emergency surgery, febrile infections), a temporary change to insulin may become necessary.

DRUG INTERACTIONS:
If Glibenclamide is taken at the same time as certain other drugs, also alcohol, there may be an undesirable potentiation or attenuation of the blood-sugar-lowering action of Glibenclamide. Therefore, other drugs should be taken only with the doctor's approval or on his prescription. Hypoglycaemic reactions as a manifestation of potentiation of the hypoglycaemic effect may occur when Glibenclamide is taken at the same time as: Beta-receptor blockers, bezafibrate, biguanides, chloramphenicol, clofibrate, coumarin derivatives, fenfluramin, MAOI, miconazole, pentoxifyline in high parenteral dosage, phenylbutazone, phenyramidol, phosphamides, salicylates, sulphinpyrazone, sulphonamides, tetracyclines. An attenuation of the hypoglycaemic action of Glibenclamide and aggravation of the metabolic state may be caused by: Laxative (chronic abuse), corticosteroids, nicotinic acid and its derivatives in high dosage, oestrogens, gestagens, phenothiazine derivatives, saluretics, sympathomimetic agents, thyroid hormones.
Alcohol may increase the hypoglycaemic effect of Glibenclamide. The amount permitted should be discussed with the doctor. Chronic alcoholism may result in a deterioration of metabolic control.

PREGNANCY AND LACTATION:
Pregnancy: There is no information on the use of Euglucon in human pregnancy but is has been in wide, general use for many years without apparent ill consequence. Animal studies have shown no hazard.
Nursing mothers: It has not been established whether Glibenclamide is excreted in human milk. Other sulphonylureas have been found in milk. There is no evidence that Glibenclamide differs from the group in this respect.

SIDE EFFECTS/ADVERSE REACTIONS:
Hypoglycaemia, leukopaenia, thrombocytopaenia, pancytopaenia, agranulocytosis, aplastic anaemia, haemolytic anaemia, thrombocytopaenic purpura, paresthesia, joint pain, nocturia. Nausea and sensations of gastric fullness are very rare. The same is true for hypersensitivity reactions of the skin and changes of the haemopoietic system (e.g. decrease in the number of platelets, white and red blood cells). Cholestasis and hepatitis may occur in isolated cases. If these side effects are experienced, the doctor will decide whether Glibenclamide treatment should be continued or not. A cross-allergy with sulphonamides and sulphonamide derivatives is possible.

SYMPTOMS AND TREATMENT OF OVERDOSE:
Overdose causes hypoglycaemia. Symptoms of hypoglycaemia are intense hunger, sweating, tremor, restlessness, irritability, depressive mood, headaches and sleep disturbances. Hypoglycaemia is nearly always promptly relieved by the intake of carbohydrates (sugar, e.g. in the form of sugar lumps, sugared fruit juices, sugared tea). Synthetic sweeteners are not suitable. The hypoglycaemia episode must be reported to the doctor as soon as possible. He will decide whether the dosage of Glibenclamide needs adjusting. If the hypoglycaemia cannot be corrected immediately, a doctor must be called urgently.
If another illness occurs during treatment with Glibenclamide, the doctor must be consulted immediately. If the diabetic sees a different doctor (e.g. if admitted to hospital or if taken ill on holiday) he must tell him that he suffers from diabetes. The treatment of diabetes requires regular checks. Until optimal control is achieved, or when changing the antidiabetic preparation, or when the tablets are not taken regularly, the patient's alertness and reactivity may be impaired to such an extent as to make him unable to cope with road traffic or operate machinery. For successful treatment, it is essential that the patient take the prescribed dose at the times stipulated by the doctor. Doses he has missed must therefore not be taken at a later time.

PACKING/PACK SIZE(S):
Blister packs of 10x10's and 100x10's.

JAUHI UBAT DARIPADA KANAK-KANAK
KEEP OUT OF REACH OF CHILDREN

MANUFACTURER/PRODUCT REGISTRATION HOLDER:
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