

GLIFEN 5mg Tablets

(Glibenclamide B.P)

GLIBENCLAMIDE is one of the oral antidiabetic agents. It stimulates the production of insulin from the pancreas and it promotes the uptake of sugar in the body cells. In diabetes the cells are not able to utilize sugar and hence it accumulates in the blood and gets passed in urine. This is the most commonly used antidiabetic tablet even though a variety of similar tablets are available.

PHARMACOKINETICS

Glibenclamide is readily absorbed from the gastrointestinal tract, peak plasma concentrations usually occurring within 2 to 4 hours, and is extensively bound to plasma proteins. Absorption may be slower in hyperglycaemic patients and may differ according to the particle size of the preparation used. It is metabolised, almost completely in the liver, the principal metabolite being only very weakly active, approximately 50% of a dose is excreted in the urine and 50% via the bile into the faeces.

INDICATIONS

Glifen is indicated as an adjunct to diet to lower the blood glucose level in patients with non-insulin dependent (Type 2) diabetes mellitus whose hyperglycaemia cannot be controlled by diet alone.

USES AND ADMINISTRATION

Glibenclamide is a sulfonylurea antidiabetic. It is given by mouth in the treatment of type 2 diabetes mellitus and has a duration of action of upto 24 hours. The usual initial dose of conventional formulations in type 2 diabetes mellitus is 2.5 to 5mg daily with breakfast, adjusted every 7 days by increments of 2.5mg daily up to 15mg daily. Although increasing the dose above 15mg is unlikely to produce further benefit, doses of up to 20mg daily have been given. Doses greater than 10mg daily may be given in 2 divided doses. Because of the relatively long duration of action of glibenclamide, it is best avoided in the elderly.

SIDE-EFFECTS

Side effects include skin rashes, photosensitivity, diarrhoea, nausea, vomiting, epigastric pain, feeling of gastric fullness, dizziness, headache, weakness, fever, hypoglycaemic reactions and paraesthesia. Eosinophilia, cholestasis, hepatitis, jaundice, blood disorders including leucopenia, thrombocytopenia, aplastic anaemia, pancytopenia, haemolytic anaemia and agranulocytosis may occur. The incidence of hypoglycaemia can be reduced if Glifen is taken with or immediately after a meal. Transient visual disturbances may occur at the commencement of treatment. Intolerance to alcohol may occur. Adjustment of dosage of Glifen may be required in patients suffering from recurrent infections, trauma, shock or after anaesthesia. When major surgery is to be performed, Glifen should be substituted with insulin therapy.

INTERACTIONS

The hypoglycaemic effects may be enhanced by: chloramphenicol, clofibrate, halofenate, cyclophosphamide, dicoumarol, monoamine oxidase inhibitors, salicylates, phenylbutazone, propranolol and other beta-adrenergic blocking agents, sulphonamides, anabolic steroids, bezafibrate, biguanides, fenfluramine, fenyramidol, miconazole, parenteral pentoxifylline in high doses, phosphamides, ACE inhibitors, fluoxetine, guanethidine, probenecid, reserpine, sulphimyraxone, tritroquaine and tetracyclines. The hypoglycaemic effect may be diminished by adrenaline, oestrogens, corticosteroids or diuretics, abuse of laxatives, high doses of nicotines, phenothiazines, saluretics, sympathomimetics and thyroid hormones. Propranolol may inhibit normal physiological response to hypoglycaemia and mask the symptoms of hypoglycaemia. Under treatment with beta-blockers as also with clonidine,

guanethidine or reserpine, the perception of the warning symptoms of a hypoglycaemic attack may be impaired. In rare instances, undesired potentiation of attenuation of the blood sugar lowering effect of Glifen have been observed during concomitant medication with H2-receptor antagonists.

ALCOHOL:

If the drug is taken at the same time as alcohol there may be either a potentiation or an attenuation of the hypoglycaemic effect.

SPECIAL PRECAUTIONS

The treatment of diabetes with Glifen requires regular follow-up checks. Until optimal control has been achieved, or when changing from one antidiabetic preparation to another, or if the tablets have not been taken regularly, alertness and reaction time may be altered to such an extent that the patient cannot safely cope with road traffic or operate machinery. Strict adherence to the diet and regularity in taking the tablets are essential to maintain physical efficiency and to prevent the blood sugar from rising too high (hyperglycaemia) or falling too low (hypoglycaemia). The signs of such underpirable changes in the blood sugar level are:

HYPERGLYCAEMIA

Severe thirst, dryness of mouth, frequent micturition, dry skin.

WARNING: "Product contains Lactose"

HYPOGLYCAEMIA

Intense hunger, sweating, tremor, restlessness, irritability, depression of mood, headaches and disturbed sleep. Artificial sweeteners are of no use for this purpose. Any hypoglycaemic reactions should be reported as soon as possible to the doctor, who will then check whether the dose of Glifen requires correction. If simple measures fail to relieve a hypoglycaemic attack promptly, a doctor should be called immediately.

CONTRA-INDICATIONS

Hypersensitivity to sulphonylureas; Diabetes mellitus in patients with a history of metabolic decompensation e.g. acidosis, diabetic precoma and coma. Diabetes mellitus complicated by fever, trauma or gangrene and in patients with impaired renal or hepatic function or serious impairment of thyroid or hepatic function or serious impairment of thyroid or adrenal function; Insulin-dependent diabetes mellitus; Diabetes mellitus in young people; Pregnancy and lactation. Women who plan to become pregnant should consult their doctor. Hypersensitivity to glibenclamide.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Hypoglycaemic symptoms, e.g. excessive perspiration, light headedness, etc. can be treated by giving the patient glucose orally or intravenously. Further treatment is symptomatic and supportive.

HOW SUPPLIED

GLIFEN TABLETS

Each film coated tablet contains: Glibenclamide B.P 5mg. Pack of 60's in blisters.

STORAGE

Store in a cool and dry place. Protect from heat, light & moisture.

Keep all medicines out of the reach of children.

To be dispensed on prescription of Registered Medical Practitioner only.

گلیفن 5 ملی گرام ٹیبلٹ
(گلیبن کلَامائیڈ) بی۔ پی

ہدایات: بخشیدی اور مشغول نہ رہیں۔ گرمی، روشنی اور نمی سے محفوظ رکھیں۔
تمام ادویات بچوں کی پہنچ سے دور رکھیں۔ صرف مستند دوا گھر کے نسخہ پر فراہم کریں۔

Manufactured by:

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