

Dibenol[®]

Glibenclamide

COMPOSITION

Dibenol[®] Tablet: Each tablet contains Glibenclamide BP 5 mg

PHARMACOLOGY

Glibenclamide appears to lower the blood glucose acutely by stimulating the release of insulin from the pancreas, an effect dependent upon functioning beta cells in the pancreatic islets. The mechanism by which Glibenclamide lowers blood glucose during long-term administration has not been clearly established. With chronic administration of Glibenclamide in Type 2 diabetic patients, the blood glucose lowering effect persists despite a gradual decline in the insulin secretory response to the drug. In addition to its blood glucose lowering actions, Glibenclamide produces a mild diuresis by enhancement of renal free water clearance

INDICATION

Dibenol[®] is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

DOSAGE AND ADMINISTRATION

There is no fixed dosage regimen for the management of diabetes mellitus with Glibenclamide or any other hypoglycemic agent.

The usual starting dose of Glibenclamide as initial therapy is 2.5 to 5 mg daily, administered with breakfast or the first main meal. Those patients who may be more sensitive to hypoglycemic drugs should be started at 1.25 mg daily. The usual maintenance dose is in the range of 1.25 to 20 mg daily, which may be given as a single dose or in divided doses. Dosage increases should be made in increments of no more than 2.5 mg at weekly intervals based upon the patient's blood glucose response. Daily doses of more than 20 mg are not recommended.

CONTRAINDICATION

Glibenclamide is contraindicated in patients:

1. With known hypersensitivity to the drug or any of its excipients.
2. With type 1 diabetes mellitus or diabetic ketoacidosis, with or without coma. These conditions should be treated with insulin.

PRECAUTION

All sulfonylurea drugs are capable of producing severe hypoglycemia. Proper patient selection, dosage, and instructions are important to avoid hypoglycemic episodes.

ADVERSE REACTION

Severe hypoglycemic reactions with coma, seizure, or other neurological impairment occur infrequently.

DRUG INTERACTION

The hypoglycemic action of sulfonylureas may be potentiated by certain drugs including nonsteroidal anti-inflammatory agents, ACE inhibitors, fluoxetine, clarithromycin, and other drugs that are highly protein bound, salicylates, sulfonamides, chloramphenicol, probenecid, monoamine oxidase inhibitors, and beta adrenergic blocking agents. When such drugs are administered to a patient receiving Glibenclamide, the patient should be observed closely for hypoglycemia. When such drugs are withdrawn from a patient receiving Glibenclamide, the patient should be observed closely for loss of control. A potential interaction between oral miconazole and oral hypoglycemic agents leading to severe hypoglycemia has been reported. Certain drugs tend to produce hyperglycemia and may lead to loss of control. These drugs include the thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blocking drugs, and isoniazid.

PREGNANCY: Pregnancy Category C

STORAGE: Store below 30°C, protected from light and moisture. Keep all medicines out of reach of children.

HOW SUPPLIED

Dibenol[®] Tablet: Each box contains 300 tablets in blister pack.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH