Kezid MR

Gliclazide BP 30 mg

Modified Release Tablet

Composition

Each modified release tablet contains Gliclazide BP 30 mg.

Description

Gliclazide is an oral antihyperglycemic agent used for the treatment of non insulin dependent diabetes mellitus (NIDDM). It belongs to the sulfonylurea class of insulin secretagogues and acts by stimulating β cells of the pancreas to release insulin as well as increases both basal insulin secretion and meal-stimulated insulin release. Gliclazide stimulates the release of insulin from pancreatic β-cells by facilitating Ca^{+2} transport across the β-cell membranes. It lowers blood glucose by stimulating the release of insulin from the pancreas, an effect dependent upon functioning β-cells in the pancreatic islets. . In type 2 diabetics, gliclazide restores the first peak of insulin secretion in response to glucose and increases the second phase of insulin secretion.

Extrapancreatic effects also may play a part in the mechanism of action of oral sulfonylurea hypoglycemic drugs. However, the mechanism of action regarding these effects is still poorly understood. Two extrapancreatic effects shown to be important in the action of Gliclazide are an increase in insulin sensitivity and a decrease in hepatic glucose production.

The anti-oxidant, platelet inhibiting and fibrinolytic actions of Gliclazide involve processes which have been implicated in the pathogenesis of vascular complications of type 2 diabetes. Gliclazide decreases microthrombosis by two mechanisms which may be involved in complications of diabetes:

- A partial inhibition of platelet aggregation and adhesion, with a decrease in the markers of platelet activation (beta thromboglobulin, thromboxane B_2);
- A restoration of the vascular endothelium fibrinolytic activity with an increase in t-PA activity.

Indications:

Type II diabetes in association with dietary measures when dietary measures alone are inadequate to control blood glucose.

Dosage and Administration:

The usual initial dose is 1 tablet (30mg) once daily, gradually increased, if necessary, upto a maximum 4 tablets (120 mg)daily in a single intake. It is recommended that the drug should be taken at breakfast time.

Switching from Kezid 80 mg tablets to Kezid 30 mg modified release tablets:

1 tablet of Kezid 80 mg is comparable to 1 tablet of Kezid MR 30 mg Tablet. Consequently the switch can be performed provided a careful blood monitoring.

Switching from another oral antidiabetic to Kezid MR 30 mg:

Take into account of dose and half-life of the previous treatment. A transitional period is not generally necessary. When switching from a hypoglycaemic sulphonylurea with a prolonged half-life, a treatment free period of a few days may be necessary to avoid an additive effect of the two products, which might cause hypoglycaemia.

Kezid MR 30 mg Tablets can be given in combination with biguanides, alpha glucosidase inhibitors or insulin. In patients not adequately controlled with Kezid MR 30 mg Tablets, concomitant insulin therapy can be initiated under close medical supervision.

Elderly (≥ 65 years of age)

Kezid MR 30 mg Tablets should be prescribed using the same dosing regimen recommended for patients under 65 years of age. Severe hypoglycemia can be induced by all sulfonylurea drugs. Elderly subjects are particularly susceptible.

Children (< 18 years of age)

Safety and effectiveness of Gliclazide modified release tablet in children have not been established.Kezid MR Tablet is therefore not recommended for use in children and adolescents.

Contraindication

Gliclazide is contraindicated to the patients with known hypersensitivity to gliclazide or other sulphonylureas, sulphonamides and combination with miconazole tablets. It is also contraindicated in type 1 diabetes, diabetic ketoacidosis, with or without coma (this condition should be treated with insulin), in case of severe renal or hepatic insufficiency. This drug is contraindicated in patients with diabetics undergoing surgery, after severe trauma, during severe infections & acute myocardial infarction.

Side effects

Side effects of gliclazide are generally mild and infrequent, including hypoglycaemia, gastrointestinal disturbances such as abdominal pain, nausea, vomiting, dyspepsia, diarrhoea, and constipation have been reported. More rarely, skin reactions including angioedema, Stevens-Johnson syndrome, changes in haematology, abnormalities of hepatic function (discontinue if jaundice appears), transient visual disturbances at start of treatment may be reported.

Precaution & Warning

All sulphonylurea drugs are capable of producing moderate to severe hypoglycaemia in cases of accidental overdose, when calorie or glucose intake is deficient, and in patients with hepatic or renal impairment. Some cases may be severe and prolonged. Hospitalisation may be necessary and glucose administration may be needed which is to be continued for several days.

The effect of gliclazide may be altered in patients with hepatic insufficiency or severe renal failure. A hypoglycaemic episode occurring in these patients may be prolonged, so appropriate management should be initiated.

Blood glucose control in a patient receiving gliclazide may be affected by fever, trauma, infection or surgical intervention. In some cases, it may be necessary to administer insulin.

Treatment of patients with G6PD-deficiency with sulphonylurea agents can lead to haemolytic anaemia. Since gliclazide belongs to the chemical class of sulphonylurea drugs, caution should be used in patients with G6PD-deficiency and a non-sulphonylurea alternative should be considered.

Use in pregnancy

Pregnancy category C. Kezid MR 30 mg tablet should not be used in pregnancy. It is recommended that insulin may be used during pregnancy in diabetic women.

Use in lactating mother

In the absence of data on the transfer of gliclazide into breast milk, and given the risk of neonatal hypoglycaemia, breast-feeding is contra-indicated during treatment with this product.

Drug Interaction

As a result of drug interaction, hypoglycemia may be potentiated when a sulfonylurea is used concurrently with agents such as: Miconazole and other azole antifungal agents, long-acting sulfonamides, NSAIDs, monoamine oxidase inhibitors, salicylates, barbiturates, beta-blockers, H2 receptor antagonists, angiotensin converting enzyme inhibitors and clarithromycin.

Certain drugs tend to induce hyperglycemia and may lead to loss of blood sugar control. These include diuretics, corticosteroids, oral contraceptives, chlorpromazine, salbutamol and nicotinic acid in pharmacologic doses.

Sulfonylureas may potentiate the action of anticoagulants. Adjustment of the anticoagulant dose may be necessary.

Overdose

An overdose of sulphonylureas may cause hypoglycaemia.

Moderate symptoms of hypoglycaemia, without any loss of consciousness or neurological signs, must be corrected by carbohydrate intake, dose adjustment and or change of diet. Strict monitoring should be continued until the physician is sure that the patient is out of danger.

Severe hypoglycaemic reactions, with coma, convulsions or other neurological disorders are possible and must be treated as a medical emergency, requiring immediate hospitalization. Dialysis is of no benefit to patients due to the strong binding of gliclazide to proteins.

Storage

Store in a cool and dry place, away from light. Keep away from children.

How Supplied

Each box contains 3x10 tablets in blister pack

Manufactured by :

KEMIKO

KEMIKO PHARMACEUTICALS LTD.

Bangladesh