DIAZID MR

Gliclazide BP

COMPOSITION

Diazid MR 30 Tablet: Each modified release tablet contains Gliclazide BP 30 mg.
Diazid MR 60 Tablet: Each modified release tablet contains Gliclazide BP 60 mg.

PHARMACOLOGY

Gliclazide is a hypoglycemic sulfonylurea oral antidiabetic. It reduces blood glucose levels by stimulating insulin secretion from the β-cells of the islets of Langerhans. It also increases in postprandial insulin and C-peptide secretion persists after two years of treatment. In addition, Gliclazide has haemovascular properties.

INDICATION

It is indicated for non-insulin-dependent diabetes (type 2) in adults when dietary measures, physical exercise and weight loss alone are not sufficient to control blood glucose.

DOSAGE AND ADMINISTRATION

The daily dose may vary from 1 to 4 tablets (30 to 120 mg), taken orally in a single intake at breakfast time. It is recommended that the tablet(s) be swallowed whole. If a dose is forgotten, there must be no increase in the dose taken the next day. As with any hypoglycemic agent, the dose should be adjusted according to the individual patient's metabolic response (blood glucose, HbA1c).

Initial dose: The recommended starting dose is 30 mg daily. If blood glucose is effectively controlled, this dose may be used for maintenance treatment. If blood glucose is not adequately controlled, the dose may be increased to 60, 90 or 120 mg daily, in successive steps. The interval between each dose increment should be at least 1 month except in patients whose blood glucose has not reduced after two weeks of treatment. In such cases, the dose may be increased at the end of the second week of treatment. The maximum recommended daily dose is 120 mg.

Switching:

From 80 mg tablet to 30 mg MR tablet: 1 tablet of 80 mg is comparable to 1 tablet of 30 mg modified release (MR) tablet. Consequently, the switch can be performed provided careful blood glucose monitoring.

From another oral antidiabetic drug to 30 mg MR tablet: 30 mg MR tablets can be used to replace other oral antidiabetic drugs. The dosage and the half-life of the previous antidiabetic drugs should be taken into account when switching to 30 mg MR tablet. A transitional period is not generally necessary. A starting dose of 30 mg should be used and this should be adjusted to suit the patient's blood glucose response, as described above.

When switching from a hypoglycemic sulfonylurea 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 hypoglycemia. The procedure described above for initiating treatment should also be used when switching to treatment with 30 mg MR tablet, i.e. a starting dose of 30 mg/day, followed by a stepwise increase in dose, depending on the metabolic response.

Combination treatment with other antidiabetic drugs: 30 mg MR tablet can be given in combination with biguanides, alpha-glucosidase inhibitors or insulin. In patients not adequately controlled with 30 mg MR tablet, concomitant insulin therapy can be initiated under close medical supervision.

CONTRAINDICATION

It is contra-indicated in the following states:-

- Hypersensitivity to Gliclazide or to any of the excipients of the product, other Sulfonylureas, Sulfonamides
- Type 1 diabetes
- Diabetic pre-coma and coma, diabetic keto-acidosis
- Severe renal or hepatic insufficiency

WARNINGS AND PRECAUTIONS

This treatment should be prescribed only if the patient is likely to have a regular food intake (including breakfast). Hypoglycemia is more likely to occur during low-calorie diets, following prolonged or strenuous exercise, alcohol intake or if a combination of hypoglycemic drugs is being used. Careful selection of patients, the dose used and clear patient directions are necessary to reduce the risk of hypoglycemic episodes.

The pharmacokinetics and pharmacodynamics of Gliclazide may be altered in patients with hepatic insufficiency or severe renal failure. A hypoglycemic episode occurring in these patients may be prolonged; so appropriate management should be initiated.

Disturbances in blood glucose, including hypoglycemia and hyperglycemia have been reported, in diabetic patients receiving concomitant treatment with fluoroquinolones, especially in elderly patients. Indeed, careful monitoring of blood glucose is recommended in all patients receiving at the same time 30 mg MR tablet and a fluoroquinolone.

Since Gliclazide belongs to the chemical class of sulfonylurea drugs, caution should be used in patients with G6PD-deficiency and a non-sulfonylurea alternative should be considered.

Cases of acute porphyria have been described with some other sulfonylurea drugs, in patients who have porphyria.

SIDE EFFECT

The most frequent side effects with Gliclazide is hypoglycemia, Gastrointestinal disturbances, including abdominal pain, nausea, vomiting, dyspepsia, diarrhoea, and constipation have been reported.

USE IN PREGNANCY AND LACTATION

As a precautionary measure, it is preferable to avoid the use of Gliclazide during pregnancy. It is unknown whether Gliclazide or its metabolites are excreted in human milk. Given the risk of neonatal hypoglycemia, the product is therefore contra-indicated in breast-feeding mothers.

USE IN CHILDREN

The safety and efficacy of it in children and adolescents have not been established. No data are available in children.

DRUG INTERACTION

Miconazole: Increases the hypoglycemic effect.
Phenylbutazone (systemic route): Increases the hypoglycemic effect of sulfonylureas.
Alcohol: Increases the hypoglycemic reaction.
Other anti-diabetic drugs: Hypoglycemia may occur in some instances.
Danazol: If the use of this drug cannot be avoided, warn the patient and emphasize the importance of urine and blood glucose monitoring.
Chlorpromazine: >100 mg per day of chlorpromazine increases blood glucose levels. Warn the patient and emphasize the importance of blood glucose monitoring.
Glucocorticoids: Increase in blood glucose levels with possible ketosis. Warn the patient and emphasize the importance of blood glucose monitoring, particularly at the start of treatment.
Ritodrine, Salbutamol, Terbutaline: Increase blood glucose levels. Emphasize the importance of monitoring blood glucose levels.
Fluoroquinolones: The patient should be warned of the risk of dysglycemia.
Anticoagulant therapy (Warfarin): Sulfonylureas may lead to potentiation of anticoagulation during concurrent treatment. Adjustment of the anticoagulant may be necessary.

OVERDOSAGE

An overdose of sulfonylureas may cause hypoglycemia.
Moderate symptoms of hypoglycemia, 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 doctor is sure that the patient is out of danger.

STORAGE

Store below 30^{O}C temperature in a dry place. Keep out of the reach of children.

HOW SUPPLIED

Diazid MR 30 Tablet: Each box contains 30 tablets in Alu-PVDC blister pack.
Diazid MR 60 Tablet: Each box contains 30 tablets in Alu-PVDC blister pack.

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NIPRO JMI Pharma

Manufactured by:
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