

SCICON-MR™

[Gliclazide]

سائیکون . ایم آر

30mg Tablets

DESCRIPTION

SCICON MR (Gliclazide) is a modified release formulation. Gliclazide is an oral hypoglycemic 2nd generation sulphonylurea which differs from other related compounds. It has an N-containing heterocyclic ring with an endocyclic bond. Chemically gliclazide is N-(hexahydrocyclopenta[c]pyrrol-2(1H)-ylcarbonyl)-4-methylbenzenesulfonamide.

COMPOSITION

Each modified release SCICON MR (Gliclazide) tablet contains Gliclazide BP.....30mg.

MECHANISM OF ACTION

Gliclazide reduces blood glucose levels by correcting both defective insulin secretion and peripheral insulin resistance (extra pancreatic effects). This occurs by closure of K⁺ channels in the β-cells of pancreas, subsequently calcium channels open, leading to increase in intracellular calcium and induction of insulin release. Gliclazide also increases the sensitivity of β₂-cells to glucose. Gliclazide also restores peripheral insulin sensitivity, such as decreasing hepatic glucose production, and increasing glucose clearance.

INDICATIONS

SCICON MR (Gliclazide) tablets are indicated for type II diabetes (Non insulin-dependent diabetes) in association with dietary measures when dietary measures alone are inadequate to control blood glucose.

DOSAGE AND ADMINISTRATION

The daily dose of SCICON MR (Gliclazide) may vary from 1 to 4 tablets per day, i.e., from 30 to 120mg 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.

The recommended starting dose is 30mg 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 120mg 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 120mg.

Switching from another oral antidiabetic agent to SCICON MR Tablets:

A transitional period is not generally necessary. A starting dose of 30mg should be used and this should be adjusted to suit the patient's blood glucose response, as described above. When switching from a hypoglycemic 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 hypoglycemia. The procedure described for initiating treatment should also be used when switching to treatment with SCICON MR (Gliclazide) tablets, i.e. a starting dose of 30mg/day, followed by a stepwise increase in dose, depending on the metabolic response.

Combination treatment with other antidiabetic agents:

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

In the elderly (over 65):

SCICON MR Tablets should be prescribed using the same dosing regimen recommended for patients under 65 years of age.

In patients with mild to moderate renal insufficiency:

The same dosing regimen can be used as in patients with normal renal function with careful patient monitoring. These data have been confirmed in clinical trials.

In patients at risk of hypoglycemia:

It is recommended that the minimum daily starting dose of 30mg is used.

DRUG INTERACTIONS

Disturbances of blood sugar control

As with all hypoglycemic, caution should be observed in administering thiazide diuretics, since these diuretics have been reported to aggravate the diabetic state. Other drugs which may adversely affect blood sugar control with hypoglycemic agents, include barbiturates, chlorpromazine, danazol, glucocorticoids, oestrogens and progestogens, salbutamol, terbutaline.

Potential of hypoglycemic effect

Certain drugs may potentiate the effect of gliclazide and thereby increase the risk of hypoglycemia. These include insulin, biguanides, sulfonamides, oxyphenbutazone, phenylbutazone, clofibrate, salicylates (high doses), coumarin derivatives, chloramphenicol, MAO's, (beta-blockers, cimetidine, ACE inhibitors, ethanol, fluconazole, captopril, enalapril, H₂-receptor antagonists, nonsteroidal anti-inflammatory agents and miconazole (Note: miconazole is contra-indicated with gliclazide). Warn the patient and emphasise the importance of self-monitoring of blood glucose levels. It may be necessary to adjust the dose of the antidiabetic agent during treatment with these substances.

Anticoagulant therapy:

Sulphonylureas may lead to potentiation of anticoagulation during concurrent treatment.

Adjustment of the anticoagulant may be necessary.

ADVERSE REACTIONS

Gliclazide is well tolerated with a low incidence of side effects. Gliclazide can cause hypoglycemia, if mealtimes are irregular and, in particular, if meal times are skipped. Possible symptoms of hypoglycemia are: headache, intense hunger, nausea, vomiting, lassitude, sleep disorders, agitation, aggression, poor concentration, reduced awareness and slowed reactions, depression, confusion, visual and speech disorders, dizziness, feeling of powerlessness, loss of self-control, delirium, convulsions, shallow respiration, bradycardia, drowsiness and loss of consciousness, possibly resulting in coma and lethal outcome.

Gastrointestinal disturbances - Nausea, diarrhea, gastric pain, constipation and vomiting.

Dermatological effects - Rash, pruritus, urticaria, erythema, maculopapular rashes and bullous reactions.

Hematological disorders - (as with other sulphonylurea drugs): a few rare cases of anemia, leucopenia, thrombocytopenia and agranulocytosis.

Miscellaneous - Headache and dizziness.

Occasional elevations of serum creatinine, blood urea nitrogen, serum bilirubin and hepatic enzymes (AST, ALT, alkaline phosphatase) levels, and exceptionally, hepatitis. Treatment should be discontinued if cholestatic jaundice appears. These symptoms usually disappear after discontinuation of treatment.

CONTRAINDICATIONS

Gliclazide is contraindicated in patients:

- With known hypersensitivity to gliclazide or to any of the components, other sulphonylureas, sulphonamides,
- With type 1 diabetes mellitus,
- With diabetic pre-coma and coma, diabetic keto-acidosis,
- With severe renal or hepatic insufficiency: in these cases the use of insulin is recommended.
- Who are being treated with miconazole.

- Who are pregnant and lactating.

PRECAUTIONS

Hypoglycemia:

Hypoglycemia is more likely to occur during low-calorie diets, following prolonged or strenuous exercise, alcohol intake or if a combination of hypoglycemic agents is being used. Hypoglycemia may occur following administration of sulphonylurea. Some cases may be severe and prolonged. Factors which increase the risk of hypoglycemia:

- Malnutrition, irregular mealtimes, skipping meals, periods of fasting or dietary changes.
- Imbalance between physical exercise and carbohydrate intake.
- Renal insufficiency.
- Severe hepatic insufficiency.
- Overdose of Gliclazide.
- Certain endocrine disorders: thyroid disorders, hypopituitarism and adrenal insufficiency.

Renal and hepatic insufficiency:

The pharmacokinetics and/or 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.

Poor blood glucose control:

Blood glucose control in a patient receiving antidiabetic treatment may be affected by any of the following: fever, trauma, infection or surgical intervention. In some cases, it may be necessary to administer insulin.

Laboratory tests:

Measurement of glycated hemoglobin levels (or fasting venous plasma glucose) is recommended in assessing blood glucose control. Blood glucose self-monitoring may also be useful.

STORAGE AND PRESENTATION:

Store below 30°C.

Protect from sunlight and moisture.

Scicon MR (Gliclazide) tablets 30mg are available in blister packs of 20's.

Keep out of reach of children.

Please read the contents carefully before use.
This package insert is continually updated from time to time.

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