Glimepiride

Acotril

2 mg Tablet

Oral Hypoglycemic

FORMULATION:
Each tablet contains:
Glimepiride ..... 2 mg

PRODUCT DESCRIPTION:
White to off-white tablet, round, biconvex, bisected on one side and plain on the other side.

Glimepiride is an oral antidiabetic agent that belongs to the class of sulfonylureas. It is used adjunctively in the management of type 2 diabetes mellitus.

PHARMACODYNAMICS AND PHARMACOKINETICS:
Glimepiride, like other sulfonylureas, lowers blood glucose levels in patients with type 2 diabetes mellitus by stimulating the release of insulin from pancreatic beta cells. Glimepiride also produces an increase in the sensitivity of peripheral tissues to insulin via an extra-pancreatic mechanism.

Following oral administration, glimepiride is readily absorbed from the gastrointestinal tract. Peak plasma concentrations occur in 2 to 3 hours. Glimepiride is highly protein bound and has a half-life of about 9 hours. It is metabolized mainly in the liver. Glimepiride is extensively metabolized to two main metabolites, a hydroxy derivative and a carboxy derivative. Glimepiride is excreted chiefly in the urine. About 60% of the dose is eliminated in the urine and 40% in the feces.

INDICATIONS:
Glimepiride is used in the treatment of type 2 diabetes mellitus.

DOSAGE AND ADMINISTRATION:
Glimepiride is used in the treatment of type 2 diabetes mellitus (NIDDM), when diet and exercise programs fail to reduce symptoms and/or blood glucose levels. Glimepiride should be considered in addition to caloric restriction weight loss and exercise.

Usual starting dose is 1-2 mg daily, given after the first main meal. The dose should then be titrated regularly or increased gradually, adjusting by 1-2 mg daily at intervals of 1-2 weeks, depending on the patient's response as well as results of fasting blood sugar. Long-term efficacy is tested with glycosylated hemoglobin assay every 3-6 months. Maintenance doses usually range from 1-4 mg per day. Maximum dose is 8 mg daily.

If the patient's hyperglycemia is not controlled with maximal doses of glimepiride, combination therapy with metformin or insulin may be considered. Frequent monitoring of blood sugar levels should be done, and the physician must strive to use the minimum doses of each drug to achieve adequate blood sugar control.

Or as prescribed by the physician.

CONTRAINDICATIONS/PRECAUTIONS/WARNINGS:
Glimepiride is contraindicated in patients with known hypersensitivity to the drug.

All sulfonylureas are capable of producing severe and prolonged hypoglycemia. Hypoglycemia should be avoided with proper patient selection, dosage, instructions concerning diet, exercise, laboratory tests and follow-up procedures. Patients with impaired renal function may be more sensitive to the glucose-lowering effect of glimepiride.

Secondary failure, or a loss of blood sugar control may occur when a patient stabilized on any diabetic regimen is exposed to stress such as fever, trauma, infection or surgery. At such times, it may be necessary to add insulin in combination with glimepiride, or even use insulin monotherapy.

Glimepiride should not be used in the treatment of insulin-dependent (type 1) diabetes mellitus. Glimepiride is contraindicated in patients with ketoacidosis (with or without coma) and in those with severe infections, trauma or either severe conditions where glimepiride is unlikely to control the hyperglycemia. Insulin should be used in such situations.

PREGNANCY AND LACTATION:
Glimepiride is contraindicated during pregnancy and must not be taken by breastfeeding women. Insulin is the preferred therapy during pregnancy.

ADVERSE DRUG REACTIONS:
As with all sulfonylureas, hypoglycemia may occur with glimepiride therapy. Hypoglycemia is more likely to occur during reduced caloric intake, following ingestion of alcohol, following intense or prolonged exercise, or when more than one glucose-lowering medication used.

Adverse effects reported with sulfonylureas were dizziness, asthenia, headache, nausea, vomiting, gastrointestinal pain, diarrhea, allergic reactions with skin rashes and pruritus, hyponatremia, leukopenia, agranulocytosis, thrombocytopenia, hemolytic anemia, aplastic anemia, and pancytopenia have also been reported with sulfonylureas.

DRUG INTERACTIONS:
Blood glucose-lowering effect of glimepiride may be potentiated by intake of the following drugs: oral antidiabetic agents, insulin, angiotensin converting enzyme inhibitors (ACEIs), coumarin derivatives, quinolones, sulfonamides, tetracyclines, chloramphenicol, monoamine oxidase inhibitors (MAOIs), cyclophosphamide, fibrates, guanethidine, high dose pentoxifylline, salicylates, phenylbutazone, sulfinpyrazone and probenecid.

Acetazolamide, corticosteroids, estrogens, progesterone, barbiturates, diuretics, epinephrine and other sympathomimetic agents, high doses of nicotinic acid, phenothiazines and phenytoin may weaken the blood glucose-lowering action of glimepiride.

Alcohol, beta-blockers, histamine-2 receptor antagonists, clonidine and reserpine may either potentiate or weaken the blood glucose-lowering effect of glimepiride.

OVERDOSE AND TREATMENT:
Glimepiride overdose can cause life-threatening hypoglycemia that necessitates immediate and aggressive treatment. Symptoms of severe hypoglycemia include extreme weakness, confusion, tremors, sweating, trouble speaking blurred vision, nausea, fainting and seizure. Emergency medical attention is required if these symptoms are experienced.

Admission to the hospital may be necessary for severe instances such as loss of consciousness or other neurological disorders.

In acute poisoning with sulfonylureas, within 1 hour of ingestion and if the patient is awake, gastric lavage should be done and/or activated charcoal should be given. Hypoglycemia should be treated with urgency.

The use of octreotide has been considered for the treatment of severe refractory cases of hypoglycemia caused by sulfonylureas.

Patients should be carefully monitored as hypoglycemia may recur or persist for several days.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

AVAILABILITY:
Foil strip x 10’s (Box of 100’s)

DR-XY34446 (AcotrilTM 2 mg)

STORE AT TEMPERATURES NOT EXCEEDING 30OC.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph.

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