Med Choice Pharma
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Glipizide

Glipdin

5 mg Tablet
ORAL HYPOGLYCEMIC

℞

FORMULATION:
Each tablet contains:
Glipizide, USP ..... 5 mg

PRODUCT DESCRIPTION:
White to off-white, round, biconvex, uncoated tablet, plain on both sides.

PHARMACODYNAMICS AND PHARMACOKINETICS:
Glipizide belongs to sulfonylurea class and has shown to lower blood glucose in humans and animals by stimulating the release of insulin from the pancreas, an effect dependent upon the functioning of beta cells in the pancreatic islets. The insulinotropic response to a meal occurs within 30 minutes after an oral dose of glipizide but elevated insulin levels do not persist beyond the time of a meal challenge. Fasting insulin levels are not elevated even on long-term administration, but postprandial insulin response continues to be enhanced after at least 6 months of treatment.

Glipizide is readily absorbed from the gastrointestinal tract with peak plasma concentrations occuring 1 to 3 hours after a single-dose. It is extensively bound to plasma proteins and has a half-life of approximately 2 to 4 hours. It is mainly metabolized in the liver and excreted chiefly in the urine, largely as inactive metabolites.

INDICATION:
Glipizide is indicated for the treatment of type 2 diabetes mellitus.

DOSAGE AND ADMINISTRATION:
Glipizide tablet is taken orally. The usual initial dose is 2.5 - 5 mg daily given as a single dose about 30 minutes before breakfast. Dosage may be adjusted at intervals of several days by amounts of 2.5 - 5 mg daily, to a maximum of 20 mg daily. Doses larger than 15 mg daily are given in two divided doses before meals.
Or as prescribed by the physician.

CONTRAINDICATIONS:
Glipizide is contraindicated in patients with ketoacidosis and in those with severe infection, trauma, or other severe conditions where sulfonylurea is unlikely to control the hyperglycemia; insulin should be administered in such situations.

PRECAUTIONS:
Sulfonylureas should not be used in type 1 diabetes mellitus. Glipizide should not be given to breastfeeding mothers. Glipizide should also be avoided in patients with impairment of renal or hepatic function. All sulfonylurea drugs are capable of producing severe hypoglycemia. Renal or hepatic impairment may cause elevated levels of glipizide causing diminished gluconeogenic capacity and increased serious hypoglycemic risk.

PREGNANCY AND LACTATION:
Pregnancy Category C.
Glipizide was found to be mildly fetotoxic in rat reproductive studies. This is similar with other sulfonylureas such as tolbutamide and tolazamide. There are no adequate and well-controlled studies in pregnant women. Glipizide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. If it is used during pregnancy, it should be discontinued at least one month before the expected delivery date. Because recent studies suggest that abnormal blood glucose levels during pregnancy are associated with a higher incidence of congenital abnormalities, many experts recommend that insulin be used during pregnancy to maintain blood glucose levels as close to normal as possible.

Although it is not known whether glipizide is excreted in human milk, some sulfonylurea drugs are known to be excreted in human milk. Because the potential for hypoglycemia in nursing infants may exist, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. If the drug is discontinued and diet is inadequate for controlling blood glucose, insulin therapy should be considered.

DRUG INTERACTIONS:
A diminished hypoglycemic effect, has been seen or might be expected on theoretical grounds with adrenaline, aminoglutethimide, chlorpromazine, corticosteroids, diazoxide, oral contraceptives, rifamycins, thiazide diuretics, and thyroid hormones.
An increased hypoglycemic effect has occurred or might be expected with ACE inhibitors, alcohol, allopurinol, some analgesics (notably azapropazone, phenylbutazone, and the salicylates), azole antifungals (fluconazole, ketoconazole, and miconazole), chloramphenicol, cimetidine, clofibrate and related compounds, coumarin anticoagualnts, fluoroquinolones, heparin, MAOIs, octreotide (although this may also produce hyperglycemia), ranitidine, sulfinpyrazone, sulfonamidess (including co-trimoxazole), tetracyclines and tricyclic antidepressants. Beta blockers have been reported both to increase hypoglycemia and to mask the typical sympathetic warning signs of hypoglycemia.

ADVERSE DRUG REACTIONS:
Gastrointestinal disturbances such as nausea, vomiting, heartburn, anorexia, diarrhea, constipation, gastralgia and a metallic taste may occur, and are usually mild and dose-dependent. Increased appetite and weight gain may occur. Cholestatic jaundice may occur rarely; glipizide should be discontinued if this occurs.
Allergic skin reactions are transient and in the form of rashes and pruritus. Photosensitivity may occur. If skin reactions persist and in severe forms such as in Stevens-Johnson Syndrome, discontinue medication and immediately contact your physician.
Leukopenia, agranulocytosis, thrombocytopenia, hemolytic anemia, aplastic anemia, and pancytopenia have been reported with sulfonylureas.
Glipizide and other sulfonylureas have reported cases of hyponatremia and syndrome of inappropriate antidiuretic hormone (SIADH) secretion.
Dizziness, drowsiness and headache have each been reported as transient reactions to glipizide and seldom require discontinuance of therapy.

OVERDOSE AND TREATMENT:
Overdosage of sulfonylureas including glipizide can produce hypoglycemia. Mild hypoglycemic symptoms without loss of consciousness or neurologic functions should be treated aggressively with oral glucose and adjustments in drug dosage and/or meal patterns. Close monitoring should continue until the physician is assured that the patient is out of danger.
Severe hypoglycemic reactions with coma, seizure, or other neurological impairment occurs infrequently but requires immediate hospitalization. If hypoglycemic coma is diagnosed or suspected, patient should be administered rapid intravenous injection of concentrated 50% glucose solution and followed by dilute 10% glucose solution to maintain blood glucose level above 100 mg / dL. Clearance of glipizide will be prolonged in hepatic disease. Because of extensive protein binding, dialysis is unlikely to be of benefit.

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

KEEP OUT OF REACH OF CHILDREN.

ADR REPORTING:
For suspected adverse drug reaction, report to the FDA: **www.fda.gov.ph**
Patient should seek medical attention at the first sign of any adverse drug reaction.

AVAILABILITY:
Alu-Clear PVC Blister Pack x 10's (Box of 100's)

REGISTRATION NUMBER:
DR-XY38042

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03 June 2010

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STORE AT TEMPERATURES NOT EXCEEDING 30°C.
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