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Metformin HCl Glibenclamide

Diacom

500mg / 5mg Film-Coated Tablet
Oral Hypoglycemic

FORMULATION

Each film-coated tablet contains:
Metformin (as Hydrochloride) ..... 500 mg
Glibenclamide ..... 5 mg

DESCRIPTION

Oblong, yellow film-coated tablet, shallow convex faces, "HD" embossed and scored on the same face.

ACTIONS AND PHARMACOLOGY

Glibenclamide: Glibenclamide is a sulfonylurea antidiabetic. It promotes the increased secretion of insulin from the beta cells of islet tissue in the pancreas by means of a process not yet specifically defined. The overall effect is a reduction in blood glucose concentration only in those patients whose pancreas is capable of synthesizing insulin. Oral antidiabetic medications apparently do not influence the production of insulin by the beta cells but seem to enhance its release from these pancreatic cells.

Metformin Hydrochloride: Metformin is an oral biguanide antidiabetic agent. Its mode of action is thought to be multifactorial and includes delayed uptake of glucose from the gastro-intestinal tract; increased peripheral glucose utilization mediated by increased insulin sensitivity; and inhibition of increased hepatic and renal gluconeogenesis.

PHARMACOKINETICS

Glibenclamide: Glibenclamide is readily absorbed from the gastrointestinal tract, peak plasma concentrations usually occurring within 2 to 4 hours, and is extensively bound to plasma proteins. Absorption may be slower in hyperglycaemic patients and may differ according to the particle size of the preparation used. It is metabolized, almost completely, in the liver, the principal metabolite being only very weakly active. Approximately 50% of a dose is excreted in the urine and 50% via the bile into the faeces.

Metformin Hydrochloride: Metformin Hydrochloride is slowly and incompletely absorbed from the gastrointestinal tract. The absolute bioavailability of a single 500mg dose is reported to be about 50 to 60%, although this is reduced somewhat if taken with food. Plasma protein binding is negligible. It is excreted unchanged in the urine. The plasma elimination half-life is reported to range from about 2 to 6 hours after oral administration.

INDICATIONS

As second-line therapy when diet, exercise and initial treatment with a sulfonylurea or metformin do not result in adequate glycemic control in patients with type 2 diabetes.

CONTRAINDICATIONS

Not recommended in patients with burns, diabetic coma, severe infection, Type 1 diabetes mellitus, ketosis, acute or chronic metabolic acidosis, including diabetic ketoacidosis with or without coma, major surgery, severe trauma, impaired hepatic or renal function; cardiovascular collapse, congestive heart failure, acute myocardial infarction or other conditions leading to hypotension or hypoxemia, infection or gangrene, pregnancy and lactation.

WARNING AND PRECAUTIONS

- Alcohol should be avoided in patients receiving metformin therapy.
- Glucose urine tests and ketone tests should be monitored.
- To be taken in conjunction with meals. Irregular mealtimes, missed meals, changes in diet may provoke hypoglycemia.
- Lactic acidosis is rare and may occur in significant renal insufficiency.
- Regular renal monitoring, especially in elderly, is needed.
- Avoid use in patients with clinical or lab evidence of hepatic disease.
- Diacom Tablet is not recommended for children.
- Diacom Tablet is capable of producing hypoglycemia or hypoglycemic symptoms, thus, proper patient selection, dosing and instructions are important to avoid potential hypoglycemic episodes.

INTERACTIONS WITH OTHER MEDICAMENTS

- Concurrent use with monoamine-oxidase inhibitors, oral anticoagulants, oxyphenbutazone, phenylbutazone and alcohol may increase glibenclamide activity.
- Co-administration of cationic drugs that are eliminated by renal tubular secretion, Furosemide, hyperglycemia-causing and hypoglycemia-causing medications and alcohol have a potential for interaction with metformin activity.
- Blood glucose levels may be increased when used concurrently with corticosteroids, epinephrine, phenytoin, thiazide diuretics and thyroid hormones.

- Co-administration of beta-adrenergic blocking agents may mask symptoms of developing hypoglycaemia thus complicating patient monitoring.
- An increased hypoglycaemic 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 anticoagulants, halofenate, heparin, MAOIs, octreotide (although this may also produce hyperglycaemia), ranitidine, sulphinpyrazone, sulphonamides (including co-trimoxazole), tetracyclines, tricyclic antidepressants, and thyroid hormones.

PREGNANCY AND LACTATION
Not recommended in pregnancy and lactation.

MAIN SIDE / ADVERSE EFFECTS
- Cross sensitivity to sulphonamides or their derivatives may occur. Transient visual disturbances may occur at the start of treatment. Reversible leucopenia and thrombocytopenia have been reported but are rare. Agranulocytosis, pancytopenia and haemolytic anaemia have been reported very rarely.
- Prolonged hypoglycaemia has been reported following the ingestion of glibenclamide.
- Long-term Metformin therapy may cause a decrease of vitamin B_{12} absorption with decrease of serum levels.
- Gastrointestinal adverse effects including anorexia, diarrhea, dyspepsia, flatulence, nausea, vomiting.
- Treatment with sulphonylureas has been associated with occasional disturbances of liver function and cholestatic jaundice. If hepatitis or cholestatic jaundice occurs, Diacom Tablet should be discontinued.

OVERDOSE
Clinical features:
Hypoglycemia and lactic acidosis.

Treatment of overdosages:
- *For mild to moderate hypoglycemia:*
  Treating with immediate ingestion of a source of glucose and counseling patient to obtain emergency medical assistance immediately.
- *For severe hypoglycemia or acute overdose, including coma:*
  - Dextrose administration is the basis of treatment of hypoglycemia.
  - Counseling patient to obtain emergency medical assistance immediately.
- *For lactic acidosis:*
  Hemodialysis with sodium bicarbonate.

DOSAGE AND ADMINISTRATION
Mode of administration:
Oral

Second-line therapy:
Usual adult dose:
Diacom 500mg / 5mg Film-Coated tablet: Initial dose of one tablet 2 times daily with meals.

If necessary, medication can be increased gradually to a maximum daily dose of 20mg glibenclamide / 2000mg metformin.

Caution: Foods, Drugs, Devices & Cosmetics Act prohibits dispensing without prescription.

Storage:
Store at temperatures not exceeding 25°C.
Protect from light and moisture.

Availability:
PVC/Alu Clear Blister Pack x 10's (Box of 120's).

Manufactured by: HOVID Bhd.
121, Jalan Tunku Abdul Rahman,
30010 Ipoh, Perak, Malaysia.

Imported & Distributed by: HOVID Inc.
Unit B, 7th Floor, Karina Building,
33 Shaw Boulevard, Pasig City,
Philippines.

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

Seek medical attention immediately at the first sign of any adverse drug reaction.

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