Size: 143 mm x 285 mm
Both side two color print

Diafit®

Metformin Hydrochloride BP

COMPOSITION:
Diafit ® 500 Tablet: Each film coated tablet contains Metformin Hydrochloride BP 500 mg.
Diafit ® 850 Tablet: Each film coated tablet contains Metformin Hydrochloride BP 850 mg.

PHARMACOLOGY:
Metformin is an antihyperglycemic agent that improves glucose tolerance in patients with type 2 diabetes, lowering both basal and postprandial plasma glucose. Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose and improves insulin sensitivity by increasing peripheral glucose uptake and utilization. Unlike sulfonylureas, Metformin does not produce hypoglycemia in either patients with type 2 diabetes or normal subjects and does not cause hyperinsulinemia.

INDICATION:
Diafit ® (Metformin Hydrochloride tablet) is indicated as an adjunct to diet and exercise to improve glycemic control in children and adults with type 2 diabetes mellitus.

DOSE & ADMINISTRATION:
Dosage of Diafit ® must be individualized on the basis of both effectiveness and tolerance, while not exceeding the maximum recommended daily dose. The maximum recommended daily dose of Diafit ® is 2550 mg in adults and 2000 mg in pediatric patients (10-16 years of age). Diafit ® should be started at a low dose, with gradual dose escalation, both to reduce gastrointestinal side effects and to permit identification of the minimum dose required for adequate glycemic control of the patient.

Recommended Dosing Schedule:
a) Adults: The usual starting dose of Diafit ® is 500 mg twice a day or 850 mg once a day, given with meals. Dosage increases should be made in increments of 500 mg weekly or 850 mg every 2 weeks, up to a total of 2000 mg per day, given in divided doses. Patients can also be titrated from 500 mg twice a day to 850 mg twice a day after 2 weeks. Doses above 2000 mg may be better tolerated given three times a day with meals.
b) Pediatrics: The usual starting dose of Diafit ® is 500 mg twice a day, given with meals. Dosage increases should be made in increments of 500 mg weekly up to a maximum of 2000 mg per day, given in divided doses. Safety and effectiveness of Diafit ® in pediatric patients below 10 years have not been established.

CONTRA-INDICATION:
Metformin is contraindicated in patients with:
1. Renal disease or renal dysfunction (e.g., as suggested by serum creatinine levels>1.5 mg/dL [male], > 1.4 mg/dL [female] or abnormal creatinine clearance).
2. Known hypersensitivity to Metformin hydrochloride.
3. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma.

WARNING AND PRECAUTION:
Lactic acidosis can occur due to Metformin accumulation during treatment with Metformin. The reported incidence of lactic acidosis in patients receiving Metformin is very low.
Metformin is known to be substantially excreted by the kidney and the risk of Metformin accumulation and lactic acidosis increases with the degree of impairment of renal function. Thus, patients with serum creatinine levels above the upper limit of normal for their age should not receive Metformin. In patients with advanced age, Metformin should be carefully titrated to establish the minimum dose for adequate glycemic effect. because aging is associated with reduced renal function.

SIDE EFFECTS:
Diarrhoea, nausea, vomiting, flatulence, indigestion, abdominal discomfort, headache etc.

USE IN PREGNANCY & LACTATION:
Pregnancy: Pregnancy Category B. Metformin tablets should not be used during pregnancy unless clearly needed.
Lactation: 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.

USE IN CHILDREN & ADOLESCENTS:
The safety and effectiveness of Metformin for the treatment of type 2 diabetes have been established in pediatric patients ages 10 to 16 years. The usual starting dose of Diafit ® 500 mg twice a day, given with meals. Dosage increases should be made in increments of 500 mg weekly up to a maximum of 2000 mg per day, given in divided doses. Safety and effectiveness of Metformin in pediatric patients below 10 years have not been established.

DRUG INTERACTION:
No information is available about the interaction of Metformin and furosemide when co-administered chronically. Nifedipine appears to enhance the absorption of Metformin. Metformin had minimal effects on nifedipine. Cationic drugs (e.g., amiloride, digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim, or vancomycin) that are eliminated by renal tubular secretion theoretically have the potential for interaction with Metformin by competing for common renal tubular transport systems. Metformin had no effect on cimetidine pharmacokinetics. Certain drugs tend to produce hyperglycemia and may lead to loss of glycemic control. These drugs include the thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blocking drugs, and isoniazid.

OVERDOSE:
Hypoglycemia has not been seen with ingestion of up to 85 grams of Metformin, although lactic acidosis has occurred in such circumstances. Hemodialysis may be useful for removal of accumulated drug from patients in whom Metformin overdose is suspected.

STORAGE:
Store in a dry and cool place below 25^0 C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:
Diafit ® 500 Tablet : Each box contains 5x10's tablets in Alu-PVC blister pack.
Diafit ® 850 Tablet : Each box contains 5x10's tablets in Alu-PVC blister pack.

Manufactured by
Team Pharmaceuticals Ltd.
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