

Glunor[®]

Metformin Hydrochloride Film Coated Tablet

DESCRIPTION

Glunor[®] is a biguanide type oral antihyperglycemic drug used in the management of type 2 diabetes. It lowers both basal and postprandial plasma glucose. Its mechanism of action is different from those of sulfonylureas and it does not produce hypoglycemia. **Glunor[®]** decreases hepatic glucose production, decreases intestinal absorption of glucose and improves insulin sensitivity by an increase in peripheral glucose uptake and utilization.

INDICATIONS

Glunor[®] as monotherapy, is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes. **Glunor[®]** is also indicated for use in combination therapy with a sulfonylurea or insulin when diet and exercise plus the single agent do not result in adequate glycemic control.

DOSAGE AND ADMINISTRATION

Adults: The usual starting dose of metformin is 500 mg twice a day or 850 mg once a day, given with meals. Dosage increase 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. For those patients requiring additional glycemic control, metformin may be given to a maximum daily dose of 2550 mg. Doses above 2000 mg may be better tolerated given three times a day with meals.

Pediatrics: Metformin can be given to pediatric diabetic patients of above 10 years of age. The usual starting dose of metformin is 500 mg twice a day, given with meals. Dosage increase - should be made in increments of 500 mg weekly, up to a maximum of 2000 mg per day, given in divided doses.

SIDE-EFFECTS

Gastrointestinal symptoms (30% patients) such as diarrhoea, nausea, vomiting, abdominal bloating, flatulence and anorexia are the most common reactions to metformin. These symptoms are generally transient and resolve spontaneously during continued treatment. Because gastrointestinal symptoms during therapy initiation appear to be dose-related, they may be decreased by gradual dose escalation and by having patients taken metformin with meals. Rarely lactic acidosis (approximately 0.03 cases/1000 patient-year) can occur due to metformin accumulation during treatment with metformin.

CONTRAINDICATIONS

Metformin is contraindicated in patients with renal dysfunction, cardiovascular collapse; acute myocardial infarction; diabetic ketoacidosis and known hypersensitivity to metformin.

PRECAUTIONS

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.

USE IN PREGNANCY AND LACTATION

Pregnancy: Safety in pregnant woman has not been established. Metformin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing mother: It is not known whether metformin is secreted in human milk. Because many drugs are excreted in human milk, it should not be administered to a breast feeding woman.

DRUG INTERACTIONS

Co-administration of furosemide, nifedipine, amiloride, digoxin, ranitidine, triamterene, and trimethoprim with metformin increase the plasma metformin concentration. Thus careful patient monitoring and dose adjustment of metformin and / or the interfering drug is recommended in patients who are taking such drugs.

OVERDOSAGE

Hypoglycemia has not been seen even 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.

PHARMACEUTICAL PRECAUTIONS

Do not store above 30 °C. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Glunor[®] 500 mg Tablet: Box containing 5 strips of 10 tablets each. Each film coated tablet contains Metformin Hydrochloride BP 500 mg.

Glunor[®] 850 mg Tablet: Box containing 10 strips of 5 tablets each. Each film coated tablet contains Metformin Hydrochloride BP 850 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

MIRPUR, DHAKA, BANGLADESH

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