METFORMIN HCl

NIDCOR TM

500 mg Film Coated Tablet

ANTIDIABETIC/HYPOGLYCEMIC

FORMULATION:
Each film coated tablet contains:
Metformin Hydrochloride .....……..... 500 mg

PHARMACOLOGICAL ACTIONS:
Metformin 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. Metformin increases the body's sensitivity to insulin. It increases activity of insulin in fat and muscle tissues.

PHARMACOKINETICS:
Metformin is well absorbed in the gastrointestinal tract. Metformin is not bound to plasma proteins.

Metformin is excreted unchanged in the urine and does not undergo hepatic metabolism. Following oral administration, approximately 90% of the absorbed drug is eliminated via the renal route within the first 24 hours, with a half-life of approximately 2 hours.

In patients with decreased renal function, the plasma and blood half-life of metformin is prolonged and the renal clearance is decreased.

INDICATIONS:
To improve glycemic control in patients with type II (non-insulin dependent diabetes mellitus). It may be given alone as an initial treatment or concomitantly with a sulfonylurea and/or insulin.

DOSAGE AND ADMINISTRATION:
Metformin should be given in divided doses with meals. Metformin should be started at low dose, usually at 500 mg once a day with meals with gradual increase, both to reduce gastrointestinal adverse effects and to permit identification of the minimum dose required for adequate glycemic control.

Dosage increases should be made at increments of 500 mg per day every 2 weeks, up to a total of 2,500 mg (2.5 g) per day, to be taken in three divided doses with meals Or as prescribed by the physician.

CONTRAINDICATIONS:
Metformin is contraindicated in patients with:
- Known hypersensitivity to metformin
- Renal disease or renal impairment
- Liver disease and chronic hypoxic lung disease
- Heart failure requiring pharmacologic treatment
- History of lactic acidosis

PRECAUTIONS:
- Metformin should be temporarily discontinued in patients undergoing radiologic studies involving intravascular administration of iodinated contrast media, because use of such products may result in acute renal dysfunction.
- Patients with renal impairment should not be given 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. In those at least 80 years of age, renal function should be monitored regularly.
- Alcohol is known to potentiate the effect of metformin on lactate metabolism.
- Metformin should be avoided in patients with evidence of hepatic disease, since impaired hepatic function has been associated with lactic acidosis.

Metformin is not recommended for use in pregnancy and in pediatric patients. Dosage of metformin should be titrated in patients with advanced age. Elderly, debilitated and malnourished patients should not be given the maximum dose. Monitoring of renal function is necessary to prevent lactic acidosis, particularly in the elderly.

DRUG INTERACTIONS:
Metformin may reduce absorption of vitamin B12 and folate in the intestine. Calcium supplementation may reverse the effect of metformin on vitamin B12 absorption.

ADVERSE/UNDESIRABLE EFFECTS:
Adverse reactions include abdominal discomfort, diarrhea, nausea, metallic taste, vomiting, flatulence, asthenia, indigestion, anorexia and headache. The following adverse reactions were reported in a few patients: abnormal stools, hypoglycemia, myalgia, light-headedness, dyspnea, nail disorder, rash, sweating, taste disorder, chest discomfort, chills, flu-like symptoms, flushing, and palpitation.

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

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

DR-XY30095

STORE AT TEMPERATURES NOT EXCEEDING 30^{O}C.

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

Pharma Nutria

Manufactured for:
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