Primera

METFORMIN HYDROCHLORIDE

SUGADROP

Rx

500 mg Film-Coated Tablet

B I G U A N I D E

FORMULATION:
Each film-coated tablet contains:
Metformin hydrochloride, USP ..... 500 mg

PRODUCT DESCRIPTION:
Metformin hydrochloride (Sugadrop) 500 mg film coated tablet is an oral antihyperglycemic agent used in the management of Type 2 diabetes. Metformin hydrochloride (Sugadrop) 500 mg film coated tablet occurs as a white to off-white, round, biconvex and plain on both sides.

PHARMACODYNAMICS:
Metformin hydrochloride is a biguanide oral antihyperglycemic agent which improves glucose tolerance in patients with type 2 diabetes mellitus, 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.

PHARMACOKINETICS:
Metformin hydrochloride is slowly and incompletely absorbed from the gastrointestinal tract, the absolute bioavailability of a single 500 mg dose is reported to be about 50-60%, although this is reduced somewhat if taken with food. Following absorption, plasma protein binding is negligibly and 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.

INDICATION:
For the treatment of Type 2 diabetes mellitus.

DOSAGE AND ADMINISTRATION:
Given by mouth in the treatment of non-insulin dependent diabetes mellitus in an initial dosage of 500 mg two or three times a day or 850 mg once or twice a day with or after meals, gradually increase if necessary to a maximum of 2 or 3 grams daily or as prescribed by the physician.

CONTRAINDICATIONS:
Diabetic coma, ketoacidosis, impaired renal function, chronic liver disease, cardiac failure, myocardial infarction, alcoholism, tissue hypoxia, lactic acidosis, severe infections, trauma, surgery and dehydration.

PRECAUTIONS:
Metformin should not be used in insulin dependent diabetes mellitus; metformin should not be used in patients with heart failure, myocardial infarction, dehydration, acute or chronic alcoholism or any other condition likely to predispose to lactic acidosis.

PREGNANCY AND LACTATION:
Metformin should not be used by pregnant and lactating women. Although metformin treatment has not been linked with adverse embryonic effects in pregnant women with diabetes, insulin rather than oral antihyperglycemic agents should be used to control hyperglycemia in pregnancy.

DRUG INTERACTIONS:
Use of biguanides concomitantly with other drugs that lower blood glucose concentration increases the risk of hypoglycemia, while drugs that increase blood glucose may reduce the effect of biguanides therapy. In general, fewer drug interactions have been reported with biguanides than with sulfonylureas. Alcohol may increase the risk of lactic acidosis as well as hypoglycemia. Care should be taken if biguanides are given concomitantly with drugs that may impair renal function.

ADVERSE EFFECTS:
Metformin causes gastrointestinal adverse effects with anorexia, nausea and vomiting. Absorption of various substances including vitamin B_{12} may be impaired. Patients may experience a metallic taste and there may be weight loss. Hypoglycemia is less of a problem with metformin than with the sulfonylureas. Lactic acidosis, sometimes fatal, has occurred but to a lesser extent than with phenformin and it is generally accepted that the lactic acidosis usually occurred in patients whose condition contraindicated the use of metformin particularly those with renal impairment.

OVERDOSE AND TREATMENT:
Overdosage
Hypoglycemia is not normally a problem encountered in metformin when used alone. In combination therapy with sulfonylurea or insulin with alcohol, hypoglycemia can occur. In excessive dosage and particularly, if there is a possibility of accumulation, lactic acidosis should be suspected. Some signs and symptoms suggestive of this condition are nausea, vomiting, diarrhea, abdominal pain and dyspnea.
Treatment
Intensive supportive therapy is recommended which should be particularly directed at correcting fluid loss and metabolic disturbance. The most effective method to remove the lactate and metformin is through hemodialysis. Lactic acidosis is a medical emergency and should be treated in the hospital.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.

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

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

ADR REPORTING STATEMENT:
"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.

REGISTRATION NUMBER:
Metformin hydrochloride (Sugadrop) 500 mg: DR-XY38628
DATE OF FIRST AUTHORIZATION:
Metformin hydrochloride (Sugadrop) 500 mg: October 13, 2010
DATE OF REVISION OF PACKAGE INSERT:
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