Glucodix ER®

Metformin Hydrochloride
Extended-Release tablet USP 500mg

Composition:
Each uncoated Extended-Release
tablet contains:
Metformin Hydrochloride USP 500 mg
Excipients Q.S.

Clinical Pharmacology
Metformin is a biguanide oral anti-hyperglycaemic agent. Its mode of action is thought to be an increased peripheral glucose utilisation mediated by increased insulin sensitivity and inhibition of hepatic and renal gluconeogenesis.

Indications
Is indicated for: Type II diabetes mellitus when diet modifications have failed and especially if the patient is overweight.
can be given alone as an initial therapy, or can be administered in combination with a sulphonylurea or an insulin.

Dosage & Administration
A modified release dose for use in adults which is given as an initial dose of 500mg once daily and may be raised in increments of 500mg at one(1) week interval to a maximum of 2000mg (2g) daily with evening meals. If glycemic control is not achieved, The dose may be administered in divided Doses of 1000mg (1g) twice daily.'

Contraindications
Hypersensitivity to metformin hydrochloride or to any of the excipients
Diabetic ketoacidosis, diabetic pre-coma, or a history thereof.
Impaired renal function
Pancreatitis
Chronic liver disease
History of or states associated with lactic acidosis such as shock or pulmonary insufficiency
Cardiac failure and recent myocardial infarction
Conditions associated with hypoxia
Hepatic insufficiency, acute alcohol intoxication, alcoholism
Pregnancy and Lactation as safety has not been established
Children as safety and efficacy have not been established.
Drug Interactions
Inadvisable combinations:
Alcohol:
Increased risk of lactic acidosis in acute alcohol intoxication, particularly in case of:-fasting or malnutrition,-hepatic insufficiency.Avoid consumption of alcohol and alcohol-containing medications.
Iodinated contrast agents
Intravascular administration of iodinated contrast agents may lead to renal failure, resulting in GLUCODIX-ER-500 accumulation and a risk of lactic acidosis.
GLUCODIX-ER-500 should be discontinued prior to, or at the time of the test and not reinstituted until 48 hours afterwards, and only after renal function has been re-evaluated and found to be normal.
Glucocorticoids (systemic and local routes), beta-2-agonists, and diuretics:
have intrinsic hyperglycaemic activity. Inform the patient and perform more frequent blood glucose monitoring, especially at the beginning of treatment. If necessary, adjust the dosage of the antidiabetic drug during therapy with the other drug and upon its discontinuation.
ACE-inhibitors may decrease the blood glucose levels. If necessary, adjust the dosage of the antidiabetic drug during therapy with the other drug and upon its discontinuation.
Cimetidine: Reduced renal clearance of GLUCODIX-ER-500 has been reported during cimetidine therapy, so a dose reduction should be considered.
Anticoagulants: GLUCODIX-ER-500 has been reported to diminish the activity of warfarin, and so dose adjustments of GLUCODIX-ER-500 should be considered.
Sulphonylurea: Concomitant therapy of GLUCODIX-ER-500 with sulphonylurea may cause hypoglycaemia.
Vitamins: Long-term treatment with GLUCODIX-ER-500 may cause vitamin B12 malabsorption in the gastro-intestinal tract, thus a dose reduction of GLUCODIX-ER-500 should be considered.

SPECIAL PRECAUTIONS:
Lactic acidosis associated with the use of GLUCODIX-ER 500 In patients with a metabolic acidosis and not having evidence of ketoacidosis (ketonuria and ketonaemia), lactic acidosis should be suspected and GLUCODIX-ER-500 therapy stopped. Lactic acidosis is a medical emergency, which must be treated in hospital. GLUCODIX-ER-500 is excreted by the kidney and regular monitoring of renal function is advised in all diabetics. GLUCODIX-ER-500 therapy should be stopped 2-3 days before surgery and before clinical investigations such as intravenous urography and intravenous angiography, and reinstated only after control of renal functions has been regained. The use of GLUCODIX-ER-500 is not advised in conditions, which may cause dehydration, or in patients suffering from serious infections, trauma or on low calorie intake. Patients on long-term treatment with GLUCODIX-ER-500 should have an annual estimation of vitamin B12 levels, since GLUCODIX-ER-500 may cause malabsorption of Vitamin B12 which may result in megaloblastic anaemia. During concomitant treatment with a sulphonylureas, blood glucose should be monitored because combined therapy may cause hypoglycaemia. Stabilisation of diabetic patients with GLUCODIX-ER-500 and insulin should be carried out in hospital because of the possibility of hypoglycaemia until the ratio of the two drugs has been obtained. Contra-Indications should be carefully observed.

Adverse Reactions Nervous System disorders:Metallic taste **Gastro-Intestinal:**Anorexia, nausea, vomiting, constipation, diarrhoeaSide effects that occur less frequently: **Haematological;**Megaloblastic anaemia
Genitourinary / Kidney: Ketoacidosis and ketonuria **Liver:** Severe cholestatic hepatitis**Other:** -
Hypersensitivity - Hypoglycaemia
Overdose
Hypoglycaemia can occur when GLUCODIX-ER-500 is given concomitantly with a sulphonylurea, insulin or alcohol. In excessive dosage, and particularly if there is a possibility of accumulation, lactic acidosis may develop. Intense symptomatic and supportive therapy is recommended which should be particularly directed at correcting fluid loss and correcting blood glucose levels.
Treatment of Overdosage:
There is no specific antidote for overdose with GLUCODIX-ER-500 . Treatment is supportive and symptomatic and should be directed at correcting fluid loss and metabolic disturbances.

Identification
White to off white coloured oblong, biconvex, both side plain extended release uncoated tablets.

Presentation
10 X 10 Alu PVC Blister pack

Storage
Store in the original package Do not store above . protect from light and moisture. Keep well closed.
KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

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