TGP°

METFORMIN HYDROCHLORIDE

GLUCOTIN

1 g Film-Coated Tablet

ORAL HYPOGLYCEMIC AGENT (BIGUANIDE)

Rx

FORMULATION:
Each Film-Coated Tablet contains:
Metformin Hydrochloride, USP.....1 g

PRODUCT DESCRIPTION:
Glucotin is a white to off-white film-coated tablet, capsule shaped, plain on one side and bisected on the other side.

PHARMACODYNAMICS:
Metformin is a biguanide with antihyperglycemic effects, lowering both basal and postprandial plasma glucose. It does not stimulate insulin secretion and therefore does not produce hypoglycemia.
Metformin may act via 3 mechanisms: in the liver, reduction of hepatic glucose production by inhibiting gluconeogenesis and glycogenolysis, in muscle, by increasing insulin sensitivity, improving peripheral glucose uptake and utilization and delay of intestinal glucose absorption.
Metformin stimulates intracellular glycogen synthesis by acting on glycogen synthase. Metformin increases the transport capacity of all types of membrane glucose transporters (GLUT). Metformin is associated with either a stable body weight or modest weight loss.
In humans, independently of its action on glycemia, metformin has favorable effects on lipid metabolism. This has been shown at therapeutic doses in controlled, medium-term or long-term clinical studies: metformin reduces total cholesterol, LDL cholesterol and triglyceride levels.
In clinical studies, use of metformin was associated with either a stable body weight or modest weight loss.

PHARMACOKINETICS:
Metformin hydrochloride is absorbed from the gastrointestinal tract. It has a plasma half-life of about 3 hours and is not bound to plasma proteins. Metformin is excreted unchanged in the urine.

INDICATIONS:
It is used in the management of maturity-onset diabetes mellitus not responsive to diet alone or diet plus the treatment with sulfonylureas.

DOSAGE AND ADMINISTRATION:
Adult:
One tablet twice daily, gradually increased if necessary to a maximum of 3 grams daily, or as prescribed by the physician.

CONTRAINDICATIONS:
Metformin hydrochloride should not be given to patients with impaired hepatic and renal function, cardiovascular collapse, congestive heart failure, acute myocardial infarction, or other conditions leading to hypotension or to hypoglycemia. It should not be given to patients with diabetes mellitus complicated with acidosis, infection, gangrene, during pregnancy or during surgery. Usage during pregnancy or lactation: It must not be used during pregnancy or by nursing mothers.

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. Drug interactions are not a problem with Metformin.

PREGNANCY AND LACTATION:
Pregnancy:
Uncontrolled diabetes during pregnancy (gestational or permanent) is associated with increased congenital abnormalities and perinatal mortality. A limited amount of data from the use of metformin in pregnant women does not indicate an increased risk of congenital abnormalities. Animal studies do not indicate harmful effects with respect to pregnancy, embryonic or fetal development, parturition or postnatal development.
However, when the patient plans to become pregnant and during pregnancy, it is recommended that prediabetes and diabetes are not treated with metformin. In diabetes, insulin should be used to maintain blood glucose levels as close to normal as possible.

Lactation:
Metformin is excreted into human breast milk in very small amounts. No adverse effects were observed in breastfed newborns/infants. However, as only limited data are available, breastfeeding is not recommended during metformin treatment.
A decision on whether to discontinue breastfeeding or to discontinue metformin needs to take into account the benefit of breastfeeding, the importance of the medicinal product to the mother, and the potential risks of adverse effects in the infant.

INCOMPATIBILITIES:
Reports of incompatibilities (if any) are not available.

DRUG INTERACTIONS:
It is reported that Metformin reduces the absorption of Vitamin B12. The serum level is not affected. Tetracyclines may precipitate Metformin lactic acidosis.

ADVERSE EFFECTS:
Metformin causes gastrointestinal adverse effects including anorexia, nausea, vomiting, and absorption of various substances including Vitamin B12 may be impaired. Patients may experience a metallic taste and there may be weight loss. Hypoglycemia is less of a protein with metformin than sulfonylureas. Lactic acidosis is sometimes fatal, has occurred to a lesser extent than with phenformin lactic acidosis usually occurred in patients whose condition contraindicated the use of metformin particularly those with renal impairment.

OVERDOSE AND TREATMENT:
Hypoglycemia has not been seen with metformin doses up to 85 g, although lactic doses has occurred in such circumstances.
High overdose of metformin or concomitant risks may lead to lactic acidosis. Lactic acidosis is a medical emergency and must be treated in a hospital. The most effective method to remove lactate and metformin is hemodialysis.

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

AVAILABILITY:
Alu-Clear PVC Blister Pack x 10's (Box of 30's)

MANUFACTURED BY: **LLOYD LABORATORIES, INC.**
No. 10 Lloyd Ave., First Bulacan Industrial City,
Malolos, Bulacan

MARKETING AUTHORIZATION HOLDER: **GAMOT PHILIPPINES, INC.**
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Quezon City, Metro Manila

EXCLUSIVELY DISTRIBUTED BY: **TGP PHARMA INC.**
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Km 14, West Service Road, Parañaque, Metro Manila

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: DR-XY38914
DATE OF RENEWAL OF AUTHORIZATION: November 26, 2020
DATE OF INSERT REVISION: January 2022