Metformin HCl

Glumet®

850 mg Film-Coated Tablet
oral hypoglycemic

℞

PRODUCT DESCRIPTION
White, capsule-shaped, biconvex, film-coated tablet, plain on one side and scored on the other side

FORMULATION
Each film-coated tablet contains:
Metformin hydrochloride, BP ……..…… 850 mg

CLINICAL PHARMACOLOGY
Pharmacodynamics
Metformin is a biguanide hypoglycemic agent lowering both basal and postprandial plasma glucose. It does not stimulate insulin secretion and as a result does not produce hypoglycemia.

Pharmacokinetics
Metformin hydrochloride (Glumet®) is slowly and incompletely absorbed from the gastrointestinal tract. A single 500-mg dose is reported to have a bioavailability of 50-60% (may be reduced in the presence of food). Plasma protein binding is negligible. It is excreted as unchanged drug in the urine. Plasma elimination half-life is reported to range from about 2 to 6 hours after oral administration.

INDICATION
Metformin hydrochloride (Glumet®) is a biguanide hypoglycemic agent used in the treatment of Non-Insulin-Dependent Diabetes Mellitus. It is given to patients who are no longer responding to sulfonylureas, either alone or in combination with sulfonylurea.

DOSAGE AND ADMINISTRATION
Adult: The usual starting dose is 500 mg or 850 mg twice or thrice daily given by mouth, with or after meals. The maximum recommended dose is 3 g daily, taken as 3 divided doses.
Children and adolescents: 1 g tablet can be used in children from 10 years of age and adolescents. Unless otherwise prescribed, the usual starting dose is one tablet of 500 mg or 850 mg once daily, given by mouth, during or after meals. The maximum recommended dose is 2 g daily, taken as 2 or 3 divided doses.
Or, as prescribed by a physician.

PRECAUTIONS AND CONTRAINDICATIONS
Metformin hydrochloride (Glumet®) should not be used in Insulin-Dependent Diabetes Mellitus. Use in Non-Insulin-Dependent Diabetes Mellitus is contraindicated in patients with ketoacidosis and in those with severe infection, stress, trauma and other severe conditions where it is unlikely to control hyperglycemia.
It should not be given in severe impairment of renal or hepatic function because of an increased risk of hypoglycemia.
It should not be used in patients with heart failure, recent myocardial infarction, dehydration, acute or chronic alcoholism or any other condition likely to predispose to lactic acidosis.

WARNING
Lactic acidosis is a rare, but serious (high mortality in the absence of prompt treatment), metabolic complication that occurs due to accumulation of metformin during treatment.

The risk of lactic acidosis must be considered in the event of non-specific signs such as muscle cramps with digestive disorders such as abdominal pain and severe asthenia. Lactic acidosis is characterized by acidotic dyspnea, abdominal pain and hypothermia followed by coma. Diagnostic laboratory findings are decreased blood pH, plasma lactate levels above 5 mmol/L, and an increased anion gap and lactate/pyruvate ratio. If metabolic acidosis is suspected, metformin should be discontinued and the patient should be hospitalized immediately.

PREGNANCY AND LACTATION
Metformin hydrochloride (Glumet®) should not be given to pregnant or lactating women since it is excreted in breast milk.

DRUG INTERACTIONS
Dosage of metformin hydrochloride (Glumet®) may be lowered in patients receiving metformin hydrochloride and cimetidine to reduce the risk of lactic acidosis. Diuretics may increase the risk of lactic acidosis due to their potential to decrease renal function. Avoid consumption of alcohol and alcohol-containing medications, as it may cause increase risk of lactic acidosis.

ADVERSE DRUG REACTIONS
The following adverse reactions may occur under treatment with metformin. Frequencies are defined as follows: **very common:** ≥1/10; **common:** ≥1/100, <1/10; **uncommon:** ≥1/1,000, <1/100; **rare:** ≥1/10,000, <1/1,000; **very rare:** <1/10,000.

Gastrointestinal disorders
Very common: nausea, vomiting, diarrhea, abdominal pain and anorexia

Nervous system disorders
Common: taste disturbance

Metabolism and nutrition disorders
Very rare: lactic acidosis (see section **WARNING**), impaired absorption of various substances including vitamin B_{12}

Skin and subcutaneous tissue disorders
Very rare: erythema, pruritus, urticaria

Hepatobiliary disorders
Very rare: liver function test abnormalities, hepatitis

OVERDOSE AND TREATMENT
Overdosage may lead to lactic acidosis. In such cases, medical emergency is required and must be treated in a hospital. The most effective way to remove lactate and metformin in the blood is hemodialysis.

STORAGE CONDITION
Keep out of reach of children.
Store at temperatures not exceeding 30°C.

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

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph **AND** Unilab at (+632) 858-1000 or productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

AVAILABILITY
Metformin hydrochloride (Glumet®) 850 mg Film-Coated Tablet, alu-PVC blister x 10s (box of 100s)

Manufactured by SYDENHAM Laboratories, Inc.
E. Aguinaldo Highway near corner
Governor's Drive, Dasmariñas, Cavite
Distributed by **UNILAB, Inc.**
No. 66 United Street, Mandaluyong City
Metro Manila, Philippines

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Reg. IPOPHIL
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