Glumil 850mg Tablet

Metformin HCl 850mg

Product Name :
Glumil 850 mg Tablet

Name and Strength of Active Substance :
Each tablet contains : Metformin Hydrochloride 850 mg

Product Description :
Round, biconvex, white film-coated tablet, engraved “850” on one side, and scored on another side.

Pharmacodynamics :
Metformin hydrochloride is a biguanide oral antihyperglycemic drug used in the management of type 2 diabetes mellitus. It decreased hepatic glucose production, decreasing intestinal absorption of glucose and improves insulin sensitivity (increases peripheral glucose uptake and utilization).

Pharmacokinetics :
The absolute bioavailability of Metformin is approximately 50% to 60%. The apparent volume of distribution (V/F) following single oral doses of Metformin hydrochloride 850 mg averaged 654±358 L. Metformin is negligibly bound to plasma proteins, in contrast to sulfonylureas, which are more than 90% protein bound. At usual clinical doses and dosing schedules, steady-state plasma concentrations of Metformin are reached within 24 to 48 hours and are generally less than 1 µg/mL. Metformin is excreted unchanged in the urine. Following oral administration, approximately 90% of the absorbed drug is eliminated in the unchanged form via the renal route within the first 24 hours, with a plasma elimination half-life of approximately 6.2 hours.

Indications :
Glumil 850 mg Tablet is an oral antidiabetic agent (biguanide) intended for the treatment of type 2 diabetes.
Glumil 850 mg Tablet may be given alone or with oral antidiabetic agents, or with insulin. A reduction of diabetic complications has been shown in overweight type 2 diabetic adult patients treated with metformin as first-line therapy after diet therapy.

Recommended Dosage :
The dosage of Glumil 850 mg Tablet is determined by your doctor on an individual basis according to the results of laboratory blood glucose measurement. The initial dosage may be increased as necessary to be one tablet 2 or 3 times daily in adults. The maximum recommended dose is 3 g daily in adults.

Renal impairment :
A GFR should be assessed before initiation of treatment with metformin containing product and at least annually thereafter. In patients at an increased risk of further progression of renal impairment and in the elderly, renal function should be assessed more frequently, e.g. every 3-6months.

GFR mL/min	Total maximum daily dose (to be divided into 2-3 daily doses)	Additional considerations
60-89	3000mg	Dose reduction may be considered in relation to declining renal function.
45-59	2000mg	Factors that may increase the risk of lactic acidosis should be reviewed before considering initiation of metformin. The starting dose is at most half of the maximum dose.
30-44	1000mg	
<30	-	Metformin is contraindicated.

Mode of administration :
Oral route.
Swallow the tablets without chewing during or at the end of meals.

Contraindications :
Hypersensitivity to metformin hydrochloride or any of the product ingredients, severe destabilisation of diabetes (ketoacidosis or pre-coma), hepatic or renal insufficiency, excessive consumption of alcoholic beverages, disease which may cause tissue hypoxia (heart failure, recent myocardial infarction, respiratory insufficiency, shock).
This drug must not be used following an X-ray examination involving the use of iodinated contrast media.
Severely reduced kidney function (GFR<30mL/min).
Any type of acute metabolic acidocis (such as lactic acidodis, diabetic ketoacidosis).

Warnings and Precautions :
Vomiting, abdominal pain accompanied by muscle cramps and/or a general feeling of malaise with severe fatigue occurring during therapy may be signs of serious destabilisation of your diabetes (diabetic ketoacidosis or lactic acidosis) requiring specific treatment.

Lactic Acidosis :
Lactic Acidosis, a very rare but serious metabolic complication, most often occurs at acute worsening of renal function or cardiorespiratory illness or sepsis. Metformin accumulation occurs at acute worsening of renal function and increases the risk of lactic acidosis.

In case of dehydration (severe diarrhea or vomiting, fever or reduced fluid intake), metformin should be temporarily

discontinued and contact with a healthcare professional is recommended.

Medicinal product that can acutely impair renal function (such as antihypertensives, diuretics and NSAIDs) should be initiated with caution in metformin-treated patients. Other risk factors for lactic acidosis are excessive alcohol intake, hepatic insufficiency, inadequately controlled diabetes, ketosis, prolonged fasting and any conditions associated with hypoxia, as well as concomitant use of medicinal products that may cause lactic acidosis.

Patients and/or care-givers should be informed of the risk of lactic acidosis. Lactic acidosis is charasterised by acidosis dyspnea, abdominal pain. Muscle cramps, asthenia and hypothermia followed by coma. In case of suspected symptoms. The patient should stop taking metformin and seek immediate medical attention. Diagnostic laboratory finding are decreased blood pH (<7.35), increased plasma lactate levels (>5mmol/L) and an increased anion gap and lactate/pyruvate ratio.

If this occurs, you should stop taking Glumil 850 mg Tablet immediately and consult your doctor promptly. Lactic acidosis is a medical emergency and must be treated in a hospital. The most effective way to remove lactate and metformin from the blood is haemodialysis.

Renal function impairment :
Metformin is known to be substantially excreted by the kidney (90%) in the unchanged form and the risk of metformin accumulation and lactic acidosis increases with the degree of impairment of renal function. Thus, do not give metformin to patients with serum creatinine levels above the upper limit of normal for their age. In patients with advanced age, carefully titrate metformin to establish the minimum dose for adequate glycemic effect, because aging is associated with reduced renal function. In elderly patients, particularly those 80 years of age and older, regularly monitor renal function and, generally, do not titrate metformin to the maximum dose.

GFR should be assessed before initiation and regularly there after (See Recommended Dosage Section). Metformin is contraindicated in patient with GFR <30mL/min and should be temporarily discontinued in the presence of condition that alter renal function (See Contraindications Section).

Interactions with Other Medicaments :
Inform your doctor or your pharmacist if you are taking or have recently taken another drug, e.g. corticosteroids, nonsteroid anti-inflammatories, antihypertensive agents of the angiotensin-converting enzyme inhibitors class, diuretics, beta2 agonists (e.g. salbutamol, terbutaline), iodinated contrast media or medications contains alcohol, even if an over-the-counter medication is involved.

Pregnancy and Lactation :
During pregnancy, treatment of diabetes is based on insulin therapy. If you discover that you are pregnant while taking Glumil 850 mg Tablet, please inform your doctor.
This drug is contraindicated during breast-feeding.

Effects on ability to drive and use machines :
No effect on the ability to drive or to use machines.

Undesirable Effects :
Gastrointestinal discomfort such as nausea, vomiting, diarrhea, abdominal pain and loss of appetite may occur especially at the beginning of treatment. These symptoms are generally transient and can be reduced by taking the tablets with meals. Should symptoms persist, stop taking the treatment and consult your doctor.

Overdosage and Treatment :
Overdose of Metformin hydrochloride has occurred after acute oral ingestion of amounts greater than 50 grams. Hypoglycemia and lactic acidosis have been reported.
Metformin hydrochloride is eliminated by dialysis, prompt hemodialysis may be useful for removal of accumulated drug.

Storage Condition :

Store below 30°C.
Keep out of reach of children.
Jauhi daripada kanak-kanak.

Packaging available :
Box of 10 x 10 Tablets

Registration No :
MAL15085008ACZ

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