

COMPOSITION :

Emlozin[®] M 5/500 Tablet: Each film coated tablet contains Empagliflozin INN 5 mg and Metformin Hydrochloride BP 500 mg

PHARMACOLOGY :

Empagliflozin is an inhibitor of Sodium-Glucose Co-Transporter 2 (SGLT2). SGLT2 is the predominant transporter, responsible for reabsorption of glucose from the kidney back into the circulation. By inhibiting SGLT2, Empagliflozin reduces renal reabsorption of filtered glucose and lowers the renal threshold for glucose and thereby increases urinary glucose excretion.

Metformin Hydrochloride is a biguanide type oral antihyperglycemic drug, used in the management of type 2 diabetes. It lowers both basal and postprandial plasma glucose. It does not produce hypoglycemia. Metformin Hydrochloride decreases hepatic glucose production, decreases intestinal absorption of glucose and improves insulin sensitivity by an increase in peripheral glucose uptake and utilization.

INDICATION :

Emlozin[®] M is indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus. Empagliflozin, when used as a component of **Emlozin[®] M**, is indicated in adults with type 2 diabetes mellitus to reduce the risk of:

- Cardiovascular death in adults with established cardiovascular disease.
- Cardiovascular death and hospitalization for heart failure in adults with heart failure.

DOSAGE & ADMINISTRATION :

The dosage of **Emlozin[®] M** should be individualized based on effectiveness and tolerability. Take **Emlozin[®] M** twice daily with meals. Dose escalation should be gradual to reduce the gastrointestinal side effects due to Metformin Hydrochloride. Maximum recommended daily dose of Metformin Hydrochloride is 2000 mg and Empagliflozin is 25mg.

Recommended individualized starting dose:

In patients on Metformin Hydrochloride, switching to this tablet containing Empagliflozin 5 mg with a similar total daily dose of Metformin Hydrochloride.

In patients on Empagliflozin, switching to this tablet containing Metformin Hydrochloride 500 mg with a similar total daily dose of Empagliflozin.

In patients already treated with Empagliflozin and Metformin Hydrochloride separately switch to this tablet containing the same total daily doses of each component. In patients with volume depletion not previously treated with Empagliflozin, correct this condition before initiating **Emlozin[®] M**.

Renal impaired patient: Assess renal function before initiating this tablet. In patients with an eGFR below 45 mL/min/1.73 m² **Emlozin[®] M** is contraindicated.

CONTRAINDICATIONS :

It is contraindicated in patients with moderate to severe renal impairment and End Stage Renal Disease (ESRD). It is also contraindicated in patients with metabolic acidosis, including diabetic ketoacidosis and patients with history of serious hypersensitivity reaction to Empagliflozin, Metformin Hydrochloride or any of the excipients in this tablet.

WARNING & PRECAUTION :

Lactic Acidosis: Postmarketing cases of Metformin Hydrochloride-associated lactic acidosis. If lactic acidosis is suspected, general supportive measures should be instituted promptly in a hospital setting, along with immediate discontinuation of this tablet. **Hypotension:** Before initiating this tablet assess and correct volume status in patients with renal impairment, the elderly, in patients with low systolic blood pressure, and in patients on diuretics. Monitor for signs and symptoms of hypotension after initiating therapy and increase monitoring in clinical situations where volume contraction is expected. **Ketoacidosis:** Before initiating this tablet assess patients who present with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level. If suspected, discontinue this tablet, evaluate and treat promptly. **Acute kidney injury & impairment in renal function:** Consider temporarily discontinuing this tablet in settings of reduced oral intake or fluid losses. If acute kidney injury occurs, discontinue this tablet promptly and institute treatment. **Urosepsis, Pyelonephritis, Fournier's gangrene & Genital mycotic infections:** Treatment with SGLT2 inhibitors increases the risk for urinary tract infections. Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated. **Hypoglycemia:** Consider lowering the dose of insulin secretagogue or insulin to reduce the risk of hypoglycemia when initiating this tablet. **Vitamin B12 Deficiency:** Metformin Hydrochloride may lower vitamin B12 levels. Monitor hematologic parameters annually. **Increased LDL-C:** Monitor and treat as appropriate. **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with this tablet.

SIDE EFFECT :

Most common adverse reactions associated with Empagliflozin (5% or greater incidence) are urinary tract infection and female genital mycotic infections. Most-common adverse reactions associated with Metformin Hydrochloride (>5%) are diarrhea, nausea/vomiting, flatulence, abdominal discomfort, indigestion, asthenia, and headache.

DRUG INTERACTION :

Carbonic Anhydrase inhibitors may increase risk of lactic acidosis. Consider more frequent monitoring. Drugs that reduce Metformin Hydrochloride clearance (such as Ranolazine, Vandetanib, Dolutegravir, and Cimetidine) may increase the accumulation of Metformin Hydrochloride. Consider the benefits and risks of concomitant use. Alcohol can potentiate the effect of Metformin Hydrochloride on lactate metabolism. Warn patients against excessive alcohol intake.

OVERDOSE :

In the event of an overdose with this tablet employ the usual supportive measures as dictated by the patient's clinical status. Removal of Empagliflozin by hemodialysis has not been studied. However, Metformin Hydrochloride is dialyzable with a clearance of up to 170 mL/min under good hemodynamic conditions. Therefore, hemodialysis may be useful party for removal of accumulated Metformin Hydrochloride from patients in whom it is overdosage is suspected.

USE IN PREGNANCY & LACTATION :

Pregnancy: Advise females of the potential risk to a fetus especially during the second and third trimesters. **Lactation:** it is not recommended when breastfeeding.

USE IN CHILDREN & ADOLESCENT :

Safety and effectiveness of this tablet in pediatric patients under 18 years of age have not been established.

STORAGE CONDITION :

Keep below 25°C temperature, protected from light & moisture. Keep out of the reach of children.

HOW SUPPLIED :

Emlozin[®] M. 5/500 Tablet: Each box contains 2X10's tablets in Alu-Alu blister pack.



Manufactured by

Team Pharmaceuticals Ltd.

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