

EmpaMet

Empagliflozin INN & Metformin Hydrochloride BP

COMPOSITION

EmpaMet 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

EmpaMet is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both Empagliflozin and Metformin Hydrochloride is appropriate. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease.

DOSAGE & ADMINISTRATION

The dosage of EmpaMet should be individualized based on effectiveness and tolerability. Take EmpaMet 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 25 mg.

Recommended individualized starting dose:

In patients on Metformin Hydrochloride, switch to EmpaMet containing Empagliflozin 5 mg with a similar total daily dose of Metformin Hydrochloride.

In patients on Empagliflozin, switch to EmpaMet 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 EmpaMet containing the same total daily doses of each component.

In patients with volume depletion not previously treated with Empagliflozin, correct this condition before initiating EmpaMet.

Renal impaired patient: Assess renal function before initiating EmpaMet. In patients with an eGFR below 45 mL/min/1.73 m² EmpaMet is contraindicated.

CONTRAINDICATIONS

EmpaMet 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 EmpaMet.

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 EmpaMet. **Hypotension:** Before initiating EmpaMet 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 EmpaMet assess patients who present with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level. If suspected, discontinue EmpaMet, evaluate and treat promptly. **Acute kidney injury & impairment in renal function:** Consider temporarily discontinuing EmpaMet in settings of reduced oral intake or fluid losses. If acute kidney injury occurs, discontinue EmpaMet 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 EmpaMet. **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 EmpaMet.

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 EmpaMet 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 partly for removal of accumulated Metformin Hydrochloride from patients in whom EmpaMet 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:** EmpaMet is not recommended when breastfeeding.

USE IN CHILDREN & ADOLESCENT

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

STORAGE CONDITION

Keep below 30°C temperature, protected from light & moisture. Keep out of the reach of children.

HOW SUPPLIED

EmpaMet 5/500 Tablet: Each box contains 30 tablets in Alu-Alu blister pack.