Empatab™ M ER

Empagliflozin INN + Metformin Hydrochloride BP Extended Release Tablet

Presentation
Empatab™ M ER 5/1000: Each extended release tablet contains Empagliflozin INN 5 mg and Metformin Hydrochloride BP 1000 mg.
Empatab™ M ER 10/1000: Each extended release tablet contains Empagliflozin INN 10 mg and Metformin Hydrochloride BP 1000 mg.
Empatab™ M ER 25/1000: Each extended release tablet contains Empagliflozin INN 25 mg and Metformin Hydrochloride BP 1000 mg.

Description
Empatab M ER is a combination of two oral antihyperglycemic drugs with complimentary mechanism of action to improve glycemic control in patients with type-2 diabetes mellitus. Empagliflozin reduces renal reabsorption of filtered glucose and lowers the renal threshold for glucose and thereby increases urinary glucose excretion and Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose and improves insulin sensitivity by an increase in peripheral glucose uptake and utilization.

Indications
Combination of Empagliflozin and Metformin extended release 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 is appropriate. Empagliflozin 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 and Administration
The starting dose of Empagliflozin and Metformin extended release formulation is individualized based on the patients current regimen. The maximum recommended total daily dose is 25 mg Empagliflozin and 2000 mg Metformin Hydrochloride. It should take once daily with a meal in the morning, dose should be increase gradually to reduce the gastrointestinal side effects due to metformin. Assessment of renal function is recommended prior to initiation of Empagliflozin and periodically thereafter.

Empatab M ER should not be initiated in patients with an eGFR less than 45 mL/min/1.73 m2. Empatab M ER may need to be discontinued at time of, or prior to, iodinated contrast imaging procedures. Empagliflozin and Metformin should not be initiated in patients with an eGFR less than 45 mL/min/1.73 m^2 .

Side-effects
Lactic acidosis, hypotension, urinary tract infection and female genital mycotic infections, diarrhea, nausea/vomiting, flatulence, abdominal discomfort, indigestion, asthenia, headache, Vitamin B12 deficiency etc.

Contraindications
Severe renal impairment (eGFR below 45 mL/min/1.73 m2), end stage renal disease, or dialysis,metabolic acidosis, including diabetic ketoacidosis.

Warning
The risk of necrotizing fasciitis of the perineum/Fournier's gangrene.

Precautions
Lactic acidosis: Lactic acidosis this can occur due to Metformin accumulation during treatment with Empagliflozin and Metformin.
Ketoacidosis: Assess patients who present with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level. If suspected, discontinue Empatab M ER, evaluate and treat promptly. Before initiating Empatab M ER, consider risk factors for ketoacidosis. Patients on Empatab M ER may require monitoring and temporary discontinuation of therapy in clinical situations known to predispose to ketoacidosis.
Volume Depletion: Before initiating Empatab M ER, assess volume status and renal function in patients with impaired renal function, elderly patients, or patients on loop diuretics. Monitor for signs and symptoms during therapy.
Urosepsis and Pyelonephritis: Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated.
Hypoglycemia: Adult patients taking an insulin secretagogue or insulin may have an increased risk of hypoglycemia. In pediatric patients 10 years of age and older, the risk of hypoglycemia was higher regardless of insulin use. Consider lowering the dosage of insulin secretagogue or insulin to reduce the risk of hypoglycemia when initiating Empatab M ER.
Genital mycotic infections: Monitoring and treatment should be done if indicated.
Vitamin B12 deficiency: Metformin may lower vitamin B12 levels. Monitor hematologic parameters annually.
Hypersensitivity Reactions: If hypersensitivity reactions occur, discontinue Empatab M ER, treat promptly, and monitor until signs and symptoms resolve.

Use in specific populations
Pregnancy: Advise females of the potential risk to a fetus especially during the second and third trimesters.
Lactation: Empagliflozin and Metformin is not recommended when breastfeeding.
Females and Males of Reproductive Potential: Advise premenopausal females of the potential for an unintended pregnancy.
Geriatric patients: Higher incidence of adverse reactions related to volume depletion and reduced renal function. Assess renal function more frequently.
Patients with renal impairment: Higher incidence of adverse reactions related to reduced renal function.
Hepatic Impairment: Avoid use in patients with hepatic impairment.

Drug interactions
• Carbonic anhydrase inhibitors may increase risk of lactic acidosis. Consider more frequent monitoring.
• Drugs that reduce metformin clearance (such as ranolazine, vandetanib, dolutegravir, and cimetidine) may increase the accumulation of metformin. Consider the benefits and risks of concomitant use.
• Alcohol can potentiate the effect of metformin on lactate metabolism. Warn patients against excessive alcohol intake.

Overdose
In the event of an overdose with Empatabh M ER contact the Doctor. Employ the usual supportive measures (e.g., remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring, and institute supportive treatment) as dictated by the patient's clinical status. Removal of Empagliflozin by hemodialysis has not been studied. However, Metformin 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 from patients in whom Empatab M overdosage is suspected.

Storage condition
Do not store above 30 °C. Keep away from light and out of the reach of children.

Commercial Pack
Empatab™ M ER 5/1000: Each box contains 5 blister strips of 6 tablets.
Empatab™ M ER 10/1000: Each box contains 5 blister strips of 6 tablets.
Empatab™ M ER 25/1000: Each box contains 3 blister strips of 6 tablets.

Manufactured by
Incepta Pharmaceuticals Ltd
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