GLIPATAB M

EMPAGLIFLOZIN INN + METFORMIN HYDROCLORIDE BP

Compositions:
Glipatab-M 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 glomerular filtrate 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 is a biguanide with anti-hyperglycemic effects, lowering both basal and postprandial plasma glucose. It does not stimulate insulin secretion and therefore does not produce hypoglycemia.

Dosage And Administration:
Individualize the starting dose is based on the patient’s current regimen: − In patients on Metformin Hydrochloride, switch to this tablet containing Empagliflozin 5 mg with a similar total daily dose of Metformin Hydrochloride; − In patients on Empagliflozin, switch 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, switch to tablet containing the same total daily doses of each component. Take this tablet twice daily with meals; with gradual dose escalation to reduce the gastrointestinal side effects due to Metformin. Adjust dosing based on effectiveness and tolerability while not exceeding the maximum recommended daily dose of Empagliflozin 25 mg and Metformin Hydrochloride 2000 mg. Geriatric Patients: Higher incidence of adverse reactions related to volume depletion and reduced renal function. Assess renal function more frequently. Renal Impairment: Empagliflozin and Metformin combination is not recommended for use in patients with an eGFR less than 45 mL/min/1.73 m².

Contraindications:
Hypersensitivity to Empagliflozin and Metformin Any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis) Diabetic pre-coma Severe renal failure (GFR <30 ml/min) Acute conditions with the potential to alter renal function such as: dehydration, severe infection, shock Disease which may cause tissue hypoxia (especially acute disease, or worsening of chronic disease) such as: decompensated heart failure, respiratory failure, recent myocardial infarction, shock Hepatic impairment, acute alcohol intoxication, alcoholism

Warning And Precaution:
Lactic Acidosis: Lactic acidosis, most often occurs at acute worsening of renal function or cardiorespiratory illness or sepsis. Diabetic ketoacidosis (DKA): Have been reported in patients treated with SGLT2 inhibitors, including Empagliflozin. Renal function: GFR should be assessed before treatment initiation and regularly thereafter. This tablet is contraindicated in patients with GFR<30 ml/min and should be temporarily discontinued in the presence of conditions that alter renal function. Cardiac function: Patients with heart failure are more at risk of hypoxia and renal insufficiency. In patients with stable chronic heart failure, this tablet may be used with a regular monitoring of cardiac and renal function. For patients with acute and unstable heart failure, this tablet is contraindicated due to the Metformin component. Surgery: Metformin must be discontinued at the time of surgery under general, spinal or epidural anesthesia. Therapy may be restarted after 48 hours of surgery or resumption of oral

nutrition and provided that renal function has been re-evaluated and found to be stable. Hypotension: Caution should be exercised in patients for whom a Empagliflozin-induced drop in blood pressure could pose a risk, such as patients with known cardiovascular disease, patients on anti-hypertensive therapy with a history of hypotension or patients aged 75 years and older. Elderly: Patients aged 75 years and older may be at an increased risk of volume depletion. Initiation of therapy in patients aged 85 years and older is not recommended due to limited experience. Urinary tract infections: Temporary interruption of treatment should be considered in patients with complicated urinary tract infections. Hepatic injury: Cases of hepatic injury have been reported with Empagliflozin in clinical trials. A causal relationship between Empagliflozin and hepatic injury has not been established.

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

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

Drug Interaction:
Diuretics: Co-administration of Empagliflozin with diuretics resulted in increased urine volume and frequency of voids, which might enhance the potential for volume depletion. Insulin or Insulin Secretagogues: Co-administration of Empagliflozin with insulin or insulin secretagogues increases the risk for hypoglycemia. Positive Urine Glucose Test: Monitoring glycemic control with urine glucose tests is not recommended in patients taking SGLT2 inhibitors. Use alternative methods to monitor glycemic control. Drugs that Reduce Metformin Clearance: Drugs that reduce Metformin clearance (such as ranolazine, vandetanib, dolutegravir, and cimetidine) may increase the accumulation of Metformin. Carbonic Anhydrase Inhibitors: Carbonic anhydrase inhibitors may increase risk of lactic acidosis. Drugs Affecting Glycemic Control: Thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blocking drugs, and isoniazid produce hoperglycemia. When such drugs are administered to a patient receiving Empagliflozin and Metformin combination, the patient should be closely observed to maintain adequate glycemic control. When such drugs are withdrawn from a patient receiving Empagliflozin and Metformin combination, the patient should be observed closely for hypoglycemia. Alcohol: Alcohol can potentiate the effect of Metformin on lactate metabolism. Warn patients against excessive alcohol intake.

Overdosage:
In the event of an overdose with Empagliflozin and Metformin 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 Empagliflozin and Metformin overdosage is suspected.

Storage:
Store in a cool (below 30° C) and dry place, protected from light and moisture. Keep out of the reach of children.

Packing:
Glipatab-M Tablet: Each box contains 3x10 tablets in Alu-Alu Blister pack.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.