Empa®

Empagliflozin INN

COMPOSITION

Empa® 10 Tablet: Each film coated tablet contains Empagliflozin INN 10 mg.
Empa® 25 Tablet: Each film coated tablet contains Empagliflozin INN 25 mg.

PHARMACOLOGY

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

Empagliflozin also reduces Sodium reabsorption and increases the delivery of Sodium to the distal tubule. This may influence several physiological functions such as lowering both pre- and afterload of the heart and downregulating sympathetic activity.

INDICATION

It is indicated in the following cases

• To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure patients.
• To reduce the risk of sustained decline in eGFR, end stage kidney disease, cardiovascular death and hospitalization in adults with chronic kidney disease at risk of progression.
• To reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease.
• 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.

Limitations of Use

• Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus. It may increase the risk of diabetic Ketoacidosis in these patients.
• Not recommended for use to improve glycemic control in patients with type 2 diabetes mellitus with an eGFR less than 30 mL/min/1.73 m^2.
• Not recommended for the treatment of chronic kidney disease in patients with polycystic kidney disease or patients requiring or with a recent history of intravenous immunosuppressive therapy or greater than 45 mg of prednisone or equivalent for kidney disease. Empagliflozin is not expected to be effective in these populations.

DOSAGE AND ADMINISTRATION

Recommended dosage is 10 mg orally once daily in the morning, taken with or without food. For additional glycemic control, dosage may be increased to 25 mg orally once daily in patients tolerating Empagliflozin.

Assess renal function before initiating and as clinically indicated. Assess volume status and correct volume depletion before initiating. Use for glycemic control is not recommended in patients with an eGFR less than 30 mL/min/1.73 m^2.

Combination therapy: When Empagliflozin is used in combination with a Sulfonylurea or with insulin, a lower dose of the Sulfonylurea or insulin may be considered to reduce the risk of hypoglycemia.

Patients with renal impairment

Empagliflozin 10 mg can be used regardless of renal function. However, due to limited experience, it is not recommended to initiate treatment with Empagliflozin in patients with an eGFR <20mL/min/1.73m^2.

Withhold Empagliflozin for at least 3 days, if possible, before major surgery or procedures associated with prolonged fasting. Resume Empagliflozin when the patient is clinically stable and has resumed oral intake.

CONTRAINDICATION

Hypersensitivity to Empagliflozin or any of the excipients in it.

WARNING AND PRECAUTION

Ketoacidosis: Consider ketone monitoring in patients at risk for Ketoacidosis. Assess for Ketoacidosis regardless of presenting blood Glucose levels and discontinue Empagliflozin if Ketoacidosis is suspected. Monitor patients for resolution of Ketoacidosis before restarting.
Volume Depletion: Before initiating Empagliflozin, 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 Empagliflozin.
Necrotizing Fasciitis of the Perineum (Fournier's Gangrene): Serious life-threatening cases have occurred in both female and male. Assess patients presenting with pain or tenderness, erythema or swelling in the genital or perineal area along with fever or malaise. If suspected, institute prompt treatment.
Genital Mycotic Infections: Monitor and treat as appropriate.
Lower Limb Amputation: Monitor patients for infections or ulcers of lower limbs and institute appropriate treatment.
Hypersensitivity Reactions: Serious hypersensitivity reactions (e.g., Angioedema) have occurred with Empagliflozin. If hypersensitivity reactions occur, discontinue Empagliflozin, treat promptly and monitor until signs and symptoms resolve.

SIDE EFFECTS

The most common side effects (5% or greater incidence) are urinary tract infections and female genital mycotic infections.

USE IN PREGNANCY AND LACTATION

Pregnancy: Advise female of the potential risk to a fetus especially during the second and third trimesters.
Lactation: Not recommended when breastfeeding.

USE IN CHILDREN AND ADOLESCENTS

The safety and effectiveness of Empagliflozin have not been established in pediatric patients less than 10 years of age as an adjunct to diet and exercise to improve glycemic control in type 2 diabetes mellitus.

DRUG INTERACTION

Diuretics: Coadministration enhances the potential for volume depletion.
Insulin or Insulin Secretagogues: Coadministration may increases the risk of hypoglycemia.
Lithium: Concomitant use may decrease serum lithium concentrations.
Positive Urine Glucose Test: Increased urinary Glucose excretion will lead to positive urine Glucose tests.
Interference with 1,5-anhydroglucitol (1,5-AG) Assay: Measurements of 1,5-AG are unreliable in assessing glycemic control in patients taking SGLT-2 inhibitors.

OVERDOSAGE

Removal of Empagliflozin by hemodialysis has not been studied.

STORAGE

Store below 30°C in a cool and dry place. Protect from light and moisture. Keep out of the reach of children.

HOW SUPPLIED

Empa® 10 Tablet: Each box contains 30 tablets in Alu-Alu Blister pack.
Empa® 25 Tablet: Each box contains 20 tablets in Alu-Alu Blister pack.

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NIPRO JMI Pharma

Manufactured by:
NIPRO JMI Pharma Ltd.
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