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 (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.

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 following cases:

• To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure.
• 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 with type 2 diabetes mellitus.

Limitations of Use:

• Not recommended 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 adults with type 2 diabetes mellitus with an eGFR less than 30 mL/min/1.73 m^2.

DOSAGE AND ADMINISTRATION

The recommended dose of it is 10 mg once daily, taken in the morning; with or without food. In patients tolerating Empagliflozin, the dose may be increased to 25 mg once daily. In patients with volume depletion, correcting this condition prior to initiation of Empagliflozin is recommended.

No dose adjustment is recommended for patients with heart failure having eGFR equal to or above 20 mL/min/1.73 m^2.

CONTRAINDICATION

• Hypersensitivity to it or any of the excipients in it.
• Patients on dialysis.

WARNING AND PRECAUTION

Ketoacidosis: Before initiating Empagliflozin, consider risk factors for ketoacidosis. Patients on Empagliflozin may require monitoring and temporary discontinuation of therapy in clinical situations known to predispose to ketoacidosis.
Volume Depletion: Before initiating it, assess volume status and renal function in patients with impaired renal function, elderly patients or patients on loop diuretics.
Urosepsis and Pyelonephritis: 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.
Necrotizing Fasciitis of the Perineum (Fournier's Gangrene): Serious life-threatening cases have occurred in both females and males. 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.
Hypersensitivity Reactions: If hypersensitivity reactions occur, discontinue it, 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 females 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 it have not been established in paediatric patients.

DRUG INTERACTION

Diuretics: Co-administration of Empagliflozin with diuretics resulted in increased urine volume.
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 as SGLT2 inhibitors increase urinary Glucose excretion and will lead to positive urine Glucose tests. Use alternative methods to monitor glycemic control.
Interference with 1,5-anhydroglucitol (1,5-AG) Assay: Monitoring glycemic control with 1,5-AG assay is not recommended as measurements of 1,5-AG are unreliable in assessing glycemic control in patients taking SGLT2 inhibitors. Use alternative methods to monitor glycemic control.

OVERDOSAGE

Removal of Empagliflozin by hemodialysis has not been studied.

STORAGE

Store below 30°C in a cool & dry place. Protect from light & 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 10 tablets in Alu-Alu Blister pack.

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NIPRO JMI Pharma

Manufactured by:
NIPRO JMI Pharma Ltd.
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