Empa™

Empagliflozin INN Tablet

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.

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.

INDICATION

Empa is indicated
- as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus and
- to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease

DOSAGE AND ADMINISTRATION

The recommended dose of **Empa** 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.

SIDE EFFECT

The most common adverse reactions associated with Empagliflozin are urinary tract infections and female genital mycotic infections. Others common side effects includes dehydration, hypotension, weakness, dizziness and increased thirstiness.

PRECAUTION

Assessment of renal function is recommended prior to initiation of Empagliflozin and periodically thereafter. Empagliflozin should not initiated in patients with an eGFR less than 45 mL/min/1.73m^2. No dose adjustment is needed in patients with an eGFR greater than or equal to 45 mL/min/1.73m^2.

CONTRAINDICATION

Empagliflozin is contraindicated in patients with history of serious hypersensitivity reaction to Empagliflozin or any of its ingredients, severe renal impairment, end-stage renal disease, or dialysis.

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.

USE IN PREGNANCY AND LACTATION

There are no adequate and well-controlled studies of Empagliflozin in pregnant women. Empagliflozin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known if Empagliflozin is excreted in human milk. It is not recommended when breastfeeding.

STORAGE CONDITION

Keep in a cool & dry place (below 30^o C), protected from light & moisture. Keep out of the reach of children.

HOW SUPPLIED

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

NIPRO JMI Pharma

Manufactured by:
NIPRO JMI Pharma Ltd.
Chauddagram, Comilla, Bangladesh.