Emazid®

Empagliflozin INN Film coated tablet

DESCRIPTION

Emazid® is a preparation of Empagliflozin. Empagliflozin is an orally-active inhibitor of the sodium-glucose co-transporter 2 (SGLT2). Sodium-glucose co-transporter 2 (SGLT2) is the predominant transporter responsible for reabsorption of glucose from the glomerular filtrate back into the circulation. Empagliflozin is an inhibitor of SGLT2. By inhibiting SGLT2, Empagliflozin reduces renal reabsorption of filtered glucose and lowers the renal threshold for glucose, and thereby increases urinary glucose excretion.

INDICATIONS

Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

DOSAGE AND ADMINISTRATION

- The recommended dose of **Emazid®** is 10 mg once daily, taken in the morning, with or without food
- Dose may be increased to 25 mg once daily
- Assess renal function before initiating **Emazid®**. Do not initiate **Emazid®** if eGFR is below 45 mL/min/1.73 m^2
- Discontinue **Emazid®** if eGFR falls persistently below 45 mL/min/1.73 m^2

CONTRAINDICATIONS

- History of serious hypersensitivity reaction to Empagliflozin
- Severe renal impairment, end-stage renal disease, or dialysis

SIDE EFFECTS

- Urinary tract infections
- Female genital mycotic infections

PRECAUTION AND WARNING

Before initiating Empagliflozin assess and correct volume status in patients with renal impairment, the elderly, in patients with low systolic blood pressure, and in patients on diuretics. Monitor for signs and symptoms during therapy. Assess patients who present with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level.

If suspected, discontinue Empagliflozin, evaluate and treat promptly. 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. Monitor renal function during therapy. More frequent monitoring is recommended in patient with eGFR below 60 mL/min/1.73 m^2.

USE IN PREGNANCY AND LACTATION

Pregnancy Category C. 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. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from Empagliflozin, a decision should be made whether to discontinue nursing or to discontinue Empagliflozin, taking into account the importance of the drug to the mother.

PHARMACEUTICAL PRECAUTION

Store below 30 ^{0}C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Emazid® 10 Tablet:
Box containing 2 strips of 10 tablets each. Each tablet contains Empagliflozin INN 10 mg.

Emazid® 25 Tablet:
Box containing 1 strip of 10 tablets each. Each tablet contains Empagliflozin INN 25 mg.

SK+F
Manufactured by
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