Emjard™

Empagliflozin

Composition: Emjard™ 10 Tablet: Each film coated tablet contains Empagliflozin INN 10 mg. **Emjard**™ 25 Tablet: Each film coated tablet contains Empagliflozin INN 25 mg.

PHARMACOLOGY: Emjard™ is a Sodium-glucose co-transporter 2 (SGLT2) inhibitor. Sodium-glucose co-transporter 2 (SGLT2) expressed in the proximal renal tubules, is responsible for the majority of the reabsorption of filtered glucose from the tubular lumen. By inhibiting SGLT2, Empagliflozin reduces reabsorption of filtered glucose and lowers the renal threshold for glucose (RTG), and thereby increases urinary glucose excretion.

INDICATION: Emjard™ is indicated:

- as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus.
- 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 **Emjard**™ is 10 mg once daily, taken in the morning, with or without food. In patients tolerating Empagliflozin 10 mg, the dose may be increased to 25 mg once daily. In patients with Hypovolumia, correcting this condition prior to initiation of Empagliflozin 10 mg is recommended.

SIDE EFFECT: The most common adverse reactions associated with Empagliflozin are urinary tract infections and female genital mycotic infections. Other common side effects include 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 be 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.

The risk of necrotizing fasciitis of the perineum/Fournier's gangrene.

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 10 mg 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: Pregnancy: There are no adequate and well-controlled studies of Empagliflozin 10 mg in pregnant women. Empagliflozin 10 mg should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Lactation: It is not known if Empagliflozin is excreted in human milk. It is not recommended when breastfeeding.

PEDIATRIC USE: Safety and effectiveness of Empagliflozin in pediatric patients under 18 years of age have not been established.

GERIATRIC USE: No dosage adjustment is recommended based on age. Empagliflozin is expected to have diminished glycemic efficacy in elderly patients with renal impairment. The risk of urinary tract infections increased in patients who were 75 years of age and older.

STORAGE CONDITION: Store below 30°C, keep away from light & moisture. Keep out of the reach of the children.

HOW SUPPLIED: Emjard™ 10 Tablet: Each box contains 20 tablets in Alu-Alu Blister pack.
Emjard™ 25 Tablet: Each box contains 10 tablets in Alu-Alu Blister pack.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH