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
- 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.

DOSAGE AND ADMINISTRATION
Prior to Initiation of Emjard®
• Assess renal function before initiating **Emjard®** and as clinically indicated
• In patients with volume depletion, correct this condition before initiating **Emjard®**
Recommended Dosage
• The recommended dose of **Emjard®** is 10 mg once daily in the morning, taken with or without food.
• For additional glycemic control, the dose may be increased to 25 mg in patients tolerating **Emjard®**.
Limitations of Use
- is not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.
- is 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. **Emjard®** is likely to be ineffective in this setting based upon its mechanism of action.
- is not recommended who have heart failure with an eGFR less than 20 mL/min/1.73 m^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.
This product contains Lactose.

ADVERSE REACTION
Important adverse reactions are described below:
a) Ketoacidosis
b) Volume Depletion
c) Urosepsis and Pyelonephritis
d) Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues
e) Necrotizing Fasciitis of the Perineum (Fournier's Gangrene)
f) Genital Mycotic Infections
g) Hypersensitivity Reactions
Other uncertain & additional adverse reactions are:
h) Gastrointestinal Disorders: Constipation
i) Infections: Necrotizing fasciitis of the perineum (Fournier's gangrene), urosepsis and pyelonephritis
j) Metabolism and Nutrition Disorders: Ketoacidosis
k) Renal and Urinary Disorders: Acute kidney injury
l) Skin and Subcutaneous Tissue Disorders: Angioedema, skin reactions (e.g., rash, urticaria)

DRUG INTERACTIONS
Clinical Impact Coadministration of empagliflozin with diuretics resulted in increased urine volume and frequency of voids, which might enhance the potential for volume depletion.
Intervention Before initiating **Emjard®**, assess volume status and renal function. In patients with volume depletion, correct this condition before initiating **Emjard®**. Monitor for signs and symptoms of volume depletion, and renal function after initiating therapy.

Insulin or Insulin Secretagogues
Clinical Impact The risk of hypoglycemia is increased when **Emjard®** is used in combination with insulin secretagogues (e.g., sulfonylurea) or insulin.
Intervention Coadministration of **Emjard®** with an insulin secretagogue (e.g., sulfonylurea) or insulin may require lower doses of the insulin secretagogue or insulin to reduce the risk of hypoglycemia.

Positive Urine Glucose Test
Clinical Impact SGLT2 inhibitors increase urinary glucose excretion and will lead to positive urine glucose tests.
Intervention Monitoring glycemic control with urine glucose tests is not recommended in patients taking SGLT2 inhibitors. Use alternative methods to monitor glycemic control.

Interference with 1,5-anhydroglucitol (1,5-AG) Assay
Clinical Impact Measurements of 1,5-AG are unreliable in assessing glycemic control in patients taking SGLT2 inhibitors.
Intervention Monitoring glycemic control with 1,5-AG assay is not recommended. Use alternative methods to monitor glycemic control.

USE IN SPECIFIC POPULATIONS
Pregnancy
Emjard® is not recommended during the second and third trimesters of pregnancy.
It can be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation
Use of **Emjard®** is not recommended while 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.

Renal Impairment
Patients with type 2 diabetes mellitus with mild and moderate renal impairment:
Mild and moderate renal impairment (eGFR 30 to less than 90 mL/min/1.73 m^2): Not recommended.
Patients without established cardiovascular disease or cardiovascular risk factors:
Not recommended when eGFR is less than 30 mL/min/1.73 m^2.
Patients with heart failure:
No dose adjustment is recommended when enrolled patients with eGFR equal to or above 20 mL/min/1.73 m^2.
Patients on dialysis:
Contraindicated.

Hepatic Impairment
Emjard® may be used in patients with hepatic impairment.

STORAGE
Store below 30°C. Protect from light & moisture. Keep out of children's reach.

HOW SUPPLIED
Emjard® 10 Tablet: Each box contains 10's/ 30's/ 50's/ 60's tablets in blister pack.
Emjard® 25 Tablet: Each box contains 10's/ 30's/ 50's/ 60's tablets in blister pack.

SQUARE