Emjard™ M

Empagliflozin and Metformin Hydrochloride

COMPOSITION:
Emjard™ M 5/500 Tablet: Each film coated tablet contains Empagliflozin INN 5 mg & Metformin Hydrochloride Ph. Eur. 500 mg.
Emjard™ M 12.5/500 Tablet: Each film coated tablet contains Empagliflozin INN 12.5 mg & Metformin Hydrochloride Ph. Eur. 500 mg.
Emjard™ M XR 5/1000 Tablet: Each extended-release tablet contains Empagliflozin INN 5 mg & Metformin Hydrochloride Ph. Eur. 1000 mg.
Emjard™ M XR 10/1000 Tablet: Each extended-release tablet contains Empagliflozin INN 10 mg & Metformin Hydrochloride Ph. Eur. 1000 mg.
Emjard™ M XR 25/1000 Tablet: Each extended-release tablet contains Empagliflozin INN 25 mg & Metformin Hydrochloride Ph. Eur. 1000 mg.

PHARMACOLOGY:
Emjard™ M combines two antihyperglycemic agents with complementary mechanisms of action to improve glycemic control in patients with type 2 diabetes: Empagliflozin, a Sodium-glucose co-transporter 2 (SGLT2) inhibitor and Metformin Hydrochloride, a member of the Biguanide class. Empagliflozin reduces reabsorption of filtered glucose and lowers the renal threshold for glucose (RTG) and thereby increases urinary glucose excretion. Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose and increases peripheral glucose uptake and utilization.

INDICATION:
Emjard™ M is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes.

DOSAGE AND ADMINISTRATION:
Individualize the starting dose of **Emjard™ M** based on the patient's current regimen. The maximum recommended dosage is 25 mg/day of Empagliflozin and 2,000 mg/day of Metformin HCl. Take orally with meals, with gradual dosage escalation to reduce the gastrointestinal side effects due to Metformin.
Emjard™ M: Take orally twice daily
Emjard™ M XR: Take orally once daily. Swallow whole; do not split, crush, dissolve, or chew.

SIDE EFFECT: Lactic Acidosis, Diabetic ketoacidosis, Dehydration, Vaginal yeast infection etc.

PRECAUTION:
Diabetic Ketoacidosis, Volume Depletion, Urosepsis and Pyelonephritis, Hypoglycemia, Fournier's Gangrene, Genital Mycotic Infections, Vitamin B_{12} Deficiency. Most common adverse reactions associated with Metformin (>5%) are diarrhea, nausea/vomiting, flatulence, abdominal discomfort, indigestion, asthenia, and headache.

CONTRAINDICATION:
- Severe renal impairment (eGFR below 30 mL/min/1.73 m^2), end stage renal disease, or on dialysis
- Metabolic acidosis, including diabetic ketoacidosis
- Hypersensitivity to Empagliflozin, Metformin or any of the excipients

DRUG INTERACTION:
- Carbonic Anhydrase Inhibitors: May increase risk of lactic acidosis.
- Drugs that Reduce Metformin Clearance: May increase risk of lactic acidosis.

USE IN PREGNANCY AND LACTATION:
Pregnancy: Not recommended during the second and third trimesters of pregnancy.
Lactation: Not recommended when breastfeeding.

PEDIATRIC USE:
The safety and effectiveness of Empagliflozin and Metformin combination has not been established in pediatric patients less than 10 years of age.

GERIATRIC USE:
The recommended dosage in geriatric patients should be usually started at the lower end of the dosage range.

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

HOW SUPPLIED:
Emjard™ M 5/500 Tablet: Each box contains 30 tablets in Blister pack.
Emjard™ M 12.5/500 Tablet: Each box contains 18 tablets in Blister pack.
Emjard™ M XR 5/1000 Tablet: Each box contains 20 tablets in Blister pack.
Emjard™ M XR 10/1000 Tablet: Each box contains 20 tablets in Blister pack.
Emjard™ M XR 25/1000 Tablet: Each box contains 20 tablets in Blister pack.

Manufactured by
SQUARE
PHARMACEUTICALS PLC.
BANGLADESH