JARDY-MET®

(Empagliflozin + Metformin HCl) Tablet

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COMPOSITION
Jardy-MET 5/500 Tablet:
Each film coated tablet contains:
Empagliflozin ..... 5 mg.
Metformin HCl (BP) ..... 500 mg.

Product Specs.: Innovator

Jardy-MET 12.5/500 Tablet:
Each film coated tablet contains:
Empagliflozin ..... 12.5 mg.
Metformin HCl (BP) ..... 500 mg.

Product Specs.: Innovator

Jardy-MET 5/1000 Tablet:
Each film coated tablet contains:
Empagliflozin ..... 5 mg.
Metformin HCl (BP) ..... 1000 mg.

Product Specs.: Innovator

Jardy-MET 12.5/1000 Tablet:
Each film coated tablet contains:
Empagliflozin ..... 12.5 mg.
Metformin HCl (BP) ..... 1000 mg.

Product Specs.: Innovator

DESCRIPTION:
It contains two oral antihyperglycemic agents: empagliflozin (SGLT2 inhibitor) and metformin hydrochloride.

CLINICAL PHARMACOLOGY:
Mechanism of action:
Empagliflozin – Selective SGLT2 inhibitor that reduces renal glucose reabsorption and increases urinary glucose excretion.
Metformin – Biguanide that lowers glucose by reducing hepatic production, decreasing intestinal absorption, and improving insulin sensitivity.
Pharmacokinetics:
Empagliflozin:
Absorption: Rapidly absorbed; peak plasma levels in ~1.5 h. Exposure increases dose-proportionally. Linear PK observed; steady state achieved without accumulation.
Distribution: Apparent Vd ~74 L; ~37% partitions into RBCs; ~86% protein bound.
Metabolism: Primarily via glucuronidation (2-O, 3-O, 6-O conjugates). No major metabolites in plasma.
Elimination: Half-life ~12 h; clearance ~10.6 L/h. Mostly excreted unchanged in feces and urine.
Metformin Hydrochloride:
Absorption: Bioavailability ~50–60% (fasting). Absorption decreases with higher doses; food lowers C_{max} (~40%), AUC (~25%), and delays T_{max} by ~35 min.
Distribution: Vd ~654 L; negligible protein binding; partitions into RBCs. Steady state within 24–48 h; plasma levels usually <1 mcg/mL.
Metabolism: Not metabolized; no hepatic or biliary excretion.
Elimination: Renal clearance ~3.5× creatinine clearance, via tubular secretion. ~90% eliminated in urine within 24 h. Plasma half-life ~6 h.

INDICATION & USAGE:
Adjunct to diet and exercise for adults with type 2 diabetes uncontrolled on empagliflozin, metformin, or both.

DOSAGE AND ADMINISTRATION:
Individualize dose based on current therapy:
- On metformin Switch to empagliflozin 5 mg + equivalent metformin dose
- On empagliflozin Switch to metformin 500 mg + equivalent empagliflozin dose
- On both Switch to equivalent doses of both components

Administration: Twice daily with meals. Gradual dose escalation reduces GI side effects of metformin.
Special considerations: Correct volume depletion before initiation (if not previously on empagliflozin).
Max daily dose: Metformin 2000 mg, Empagliflozin 25 mg.
CONTRAINDICATIONS:
Renal impairment:
- Serum creatinine ≥1.5 mg/dL (males), ≥1.4 mg/dL (females), or eGFR <45 mL/min/1.73 m²
- ESRD or dialysis
- Conditions causing renal failure (e.g., shock, acute MI, septicemia)

Metabolic acidosis:
- Acute or chronic, including diabetic ketoacidosis (DKA) treat DKA with insulin

Hypersensitivity:
- History of serious reaction to empagliflozin or metformin

WARNINGS & PRECAUTIONS:
Lactic acidosis (metformin): Rare, ~50% fatal; risk with renal/hepatic impairment, hypoxemia, dehydration, sepsis, alcohol, or contrast.
Hypotension (empagliflozin): From volume loss; higher risk in elderly, renal impairment, low BP, or diuretics.
Renal: Empagliflozin increases creatinine, decreases eGFR; metformin accumulates causing lactic acidosis. Contraindicated if eGFR <45 mL/min/1.73 m².
- Avoid use in hepatic impairment
- Hypoglycemia
- Higher risk of genital mycosis and UTIs; monitor and treat
- Long-term metformin may reduce Vitamin B_{12}; monitor if anemia or neuropathy.
- ***Alcohol:*** Excess increases lactic acidosis risk

DRUG INTERACTIONS:
Cimetidine, digoxin, quinidine, vancomycin, etc., may raise metformin levels; monitor.
Topiramate and acetazolamide may increase lactic acidosis with metformin; use cautiously.
Hyperglycemia risk: Diuretics, corticosteroids, thyroid agents, estrogens, OCPs, phenytoin, niacin, sympathomimetics, calcium channel blockers, and isoniazid.

USE IN SPECIFIC POPULATION:
- ***Pregnancy (C):*** Use only if benefits outweigh risks.
- ***Nursing:*** Metformin in human milk (low); empagliflozin unknown. Decide between nursing or therapy.
- ***Pediatric:*** Not established <18 yrs.
- ***Geriatric:*** Monitor renal function closely; adjust dose.

ADVERSE REACTIONS:
The following important adverse reactions are described below and elsewhere in the labeling:
Lactic Acidosis:
Hypotension / Volume depletion, Increased urination / Impairment in Renal Function, Impaired Hepatic functions, Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues, Genital Mycotic Infections, Urinary Tract Infections, Vitamin B_{12} Deficiency, Increased Low-Density Lipoprotein Cholesterol (LDL-C).

OVER DOSAGE:
In case of overdose, contact a hospital immediately. Manage with supportive care, including gastrointestinal decontamination, clinical monitoring, and treatment as needed.

INSTRUCTIONS:
– Store below 30°C.
– Protect from heat, sunlight & moisture.
– Keep out of the reach of children.
– To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:

JARDY-MET 5/500 Tablet	:	Pack of 2 x 7 tablets.
JARDY-MET 12.5/500 Tablet	:	Pack of 2 x 7 tablets.
JARDY-MET 5/1000 Tablet	:	Pack of 2 x 7 tablets.
JARDY-MET 12.5/1000 Tablet	:	Pack of 2 x 7 tablets.

ہدایات:
۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی، دھوپ اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔

Manufactured by:
CCL Pharmaceuticals (Pvt.) Ltd.
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FOR FURTHER INFORMATION PLEASE CONTACT:

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