

JARDY™

[E M P A G L I F L O Z I N]

COMPOSITION

Jardy Tablet 10 mg:

Each film coated tablet contains:
Empagliflozin 10 mg.

Product Specs.: Innovator

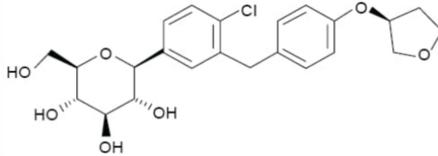
Jardy Tablet 25 mg:

Each film coated tablet contains:
Empagliflozin 25 mg.

Product Specs.: Innovator

DESCRIPTION:

JARDY tablets contain empagliflozin, an orally-active inhibitor of the sodium-glucose co-transporter 2 (SGLT2). The chemical name of empagliflozin is D-Glucitol,1,5-anhydro-1-C-[4-chloro-3-[[4-[[[(3S)-tetrahydro-3 furanyl]oxy]phenyl]methyl]phenyl]-, (1S). Its molecular formula is C₂₃H₂₇ClO₇ and the molecular weight is 450.91. The structural formula is:



CLINICAL PHARMACOLOGY:

Mechanism of Action:

Empagliflozin, an SGLT2 inhibitor, blocks renal glucose reabsorption, lowers the renal threshold for glucose, and increases urinary glucose excretion.

Pharmacokinetics:

Absorption: After oral administration, peak plasma concentration occurs at ~1.5 h. At steady state, AUC and C_{max} were 1870 nmol·h/L and 259 nmol/L (10 mg) and 4740 nmol·h/L and 687 nmol/L (25 mg). Can be taken with or without food.

Distribution: Volume of distribution: 73.8 L; plasma protein binding: 86.2%.

Metabolism: Primarily metabolized by glucuronidation (UGT2B7, UGT1A3, UGT1A8, UGT1A9).

Elimination: Half-life ~12.4 h; clearance 10.6 L/h. About 95.6% excreted via feces (41.2%, mostly unchanged) and urine (54.4%, ~50% unchanged).

Special Populations:

Renal impairment: In patients with mild (eGFR: 60 to less than 90 mL/min/1.73 m²), moderate (eGFR: 30 to less than 60 mL/min/1.73 m²), and severe (eGFR: less than 30 mL/min/1.73 m²) renal impairment and subjects with kidney failure/end stage renal disease (ESRD) patients, AUC of empagliflozin increased by approximately 18%, 20%, 66%, and 48%, respectively

Hepatic impairment: In subjects with mild, moderate, and severe hepatic impairment according to the Child-Pugh classification, AUC of empagliflozin increased by approximately 23%, 47%, and 75%, and C_{max} increased by approximately 4%, 23%, and 48%, respectively.

Age, BMI, gender, race: No clinically significant effect.

INDICATIONS AND USAGE:

It is indicated;

- Adjunct to diet and exercise for glycemic control in adults with type 2 diabetes.
- Reduces risk of cardiovascular death in adults with type 2 diabetes and established CVD.

It is not recommended for type 1 diabetes or treatment of diabetic ketoacidosis

DOSAGE AND ADMINISTRATION:

The recommended dose of JARDY is 10 mg once daily in the morning, taken with or without food. In patients tolerating JARDY, the dose may be increased to 25 mg. In patients with volume depletion, correcting this condition prior to initiation of JARDY is recommended

Patients with Renal Impairment:

- Assess renal function before starting and periodically.
- Do not initiate if eGFR <45 mL/min/1.73 m².
- No dose adjustment needed if eGFR ≥45 mL/min/1.73 m².
- Discontinue if eGFR falls <45 mL/min/1.73 m².

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CONTRAINDICATIONS:

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

WARNINGS AND PRECAUTIONS:

- **Hypotension:** May occur due to volume contraction, especially in elderly, renal impairment, low BP, or on diuretics.
- **Ketoacidosis:** Can occur even with glucose <250 mg/dL. Discontinue if suspected; initiate prompt treatment (insulin, fluids, carbs).
- **Acute Kidney Injury:** Risk increased with hypovolemia, renal insufficiency, CHF, or concomitant nephrotoxic drugs. Temporarily discontinue in acute illness, fasting, or fluid loss. Monitor renal function closely if eGFR <60. Not recommended if eGFR <45; contraindicated if <30.
- **UTIs (Urosepsis/Pyelonephritis):** Increased risk; evaluate and treat promptly.
- **Hypoglycemia (with Insulin/Secretagogues):** Risk increased; dose adjustment of insulin or secretagogue may be needed.
- **Genital Mycotic Infections:** Higher risk, especially with history of recurrent infections; monitor and treat as needed.
- **LDL-C Increase:** May occur; monitor and manage appropriately.

DRUG INTERACTIONS:

Diuretics: May increase urine volume/frequency leading to higher risk of volume depletion.

Insulin/Secretagogues: Increased risk of hypoglycemia; dose adjustment may be required.

USE IN SPECIFIC POPULATION:

Pregnancy:

Not recommended during the second and third trimesters. Limited human data; risks cannot be ruled out. Poorly controlled diabetes in pregnancy poses risks to mother and fetus.

Nursing mothers:

Use is not recommended while breastfeeding due to potential for serious adverse effects in infants.

Pediatric use:

Safety and efficacy not established in patients under 18 years.

Geriatric use:

No dosage adjustment based on age. Reduced glycemic efficacy expected with renal impairment. Risk of volume depletion and UTIs is higher in patients ≥75 years.

Renal impairment:

Glycemic benefit decreases with worsening renal function. Risks of renal impairment, volume depletion, and UTIs increase. Not effective or recommended in severe renal impairment, ESRD, or dialysis.

Hepatic impairment:

May be used in patients with hepatic impairment.

ADVERSE REACTIONS:

The following important adverse reactions are:

- Hypotension
- Ketoacidosis
- Acute Kidney Injury and Impairment in Renal Function
- Urosepsis and Pyelonephritis
- Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues
- Genital Mycotic Infections
- Increased Low-Density Lipoprotein Cholesterol (LDL-C)

Post-marketing experience:

Additional adverse reactions have been identified during post approval use of empagliflozin.

- Ketoacidosis
- Urosepsis and pyelonephritis

OVERDOSAGE: In the event of an overdose, employ supportive measures, as dictated by the patient's clinical status.

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 Tablet 10 mg : Pack of 1 x 14 tablets.

Jardy Tablet 25 mg : Pack of 1 x 14 tablets.

Manufactured by:
CCL Pharmaceuticals (Pvt.) Ltd.
Plot No. 710, Sundar Industrial Estate, Raiwind Road Lahore, Pakistan.

FOR FURTHER INFORMATION PLEASE CONTACT:

 Manufactured for:
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62 Industrial Estate, Kot Lakhpat, Lahore, Pakistan.

ہدایات:

۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

گرمی، دھوپ اور نمی سے بچائیں۔

بچوں کی پہنچ سے دور رکھیں۔

صرف متند ڈاکٹر کے نسخہ پر فروخت کریں۔