

# Jardian®

Empagliflozin  
Tablet

## Description

Empagliflozin is an orally active SGLT-2 (sodium-glucose co-transporter 2) receptor antagonist, which targets the kidney for the excretion of excess glucose.

## Indications

Empagliflozin is indicated as an adjunct to diet and exercise for the treatment of type-2 diabetes. It can be given alone or in combination with other oral antidiabetic agents. It is also indicated for reduction in cardiovascular risk in type-2 diabetic patients.

## Dosage and Administration

The usual recommended starting dose of Empagliflozin is 10 mg once daily in the morning. The dosage of Empagliflozin can be increased to 25 mg once daily. Empagliflozin may be administered with or without food.

## Contraindications

Empagliflozin is contraindicated in patients with a history of serious hypersensitivity to Empagliflozin or any of its components, severe renal impairment, end stage renal disease, or dialysis.

## Precautions

Empagliflozin should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

For renal impaired patients, 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/1.73 m<sup>2</sup>. No dose adjustment is needed in patients with an eGFR greater than or equal to 45 ml/min/1.73 m<sup>2</sup>. Empagliflozin should be discontinued if eGFR is persistently less than 45 ml/min/1.73m<sup>2</sup>.

Cases of hepatic injury have been reported with Empagliflozin in clinical trials.

Osmotic diuresis accompanying therapeutic glucosuria may lead to a modest decrease in blood pressure. Therefore, caution should be exercised in patients with known cardiovascular disease, patients on anti-hypertensive therapy with a history of hypotension.

In case of conditions that may lead to fluid loss (e.g. gastrointestinal illness), careful monitoring of volume status and electrolytes is recommended. Temporary interruption of treatment with Empagliflozin should be considered until the fluid loss is corrected. Temporary interruption of Empagliflozin should be considered in patients with complicated urinary tract infections.

**Adverse Effects**

The most common adverse effects associated with Empagliflozin are hypoglycemia (when used with sulphonylurea or insulin), hypotension, ketoacidosis, genital mycotic infections, urinary tract infections including urosepsis and pyelonephritis, increased urination, increased LDL-C.

**Use in Special Population****Pregnancy & Lactation**

There are no adequate and well controlled studies of Empagliflozin in pregnant women. It should not be used in pregnant women except if the potential benefit justifies the potential risk to the fetus. It is not known if Empagliflozin is excreted in human milk, and so is not recommended during breastfeeding.

**Pediatric Patients**

The safety and effectiveness of Jardian® in pediatric patients under 18 years of age have not been established.

**Geriatric Patients**

No dose adjustment is recommended based on age. In patients 75 years and older, an increased risk for volume depletion and urinary tract infections should be taken into account.

**Drug Interactions****Diuretics**

Empagliflozin may add to the diuretic effect of thiazide and loop diuretics and may increase the risk of dehydration and hypotension.

**Insulin and insulin secretagogues**

Insulin and insulin secretagogues, such as sulfonylureas, may increase the risk of hypoglycaemia. Therefore, a lower dose of insulin or an insulin secretagogue may be required to reduce the risk of hypoglycaemia when used in combination with empagliflozin.

**Pharmaceutical Precaution**

Keep in a cool and dry place. Keep out of the reach of children. Protect from light.

**Commercial Pack**

Jardian® 10 Tablet: Box containing 20 tablets in 2X10's blister strips. Each film coated tablet contains Empagliflozin INN 10 mg.

Jardian® 25 Tablet: Box containing 10 tablets in 1X10's blister strips. Each film coated tablet contains Empagliflozin INN 25 mg.

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