Jardimet® 5/500

Empagliflozin & Metformin Hydrochloride
Tablet

Description

Jardimet® is a combination of Empagliflozin, a Sodium-glucose cotransporter-2 (SGLT2) inhibitor and Metformin Hydrochloride, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both Empagliflozin and Metformin Hydrochloride is appropriate.

Indications

Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. However, the effectiveness of Empagliflozin and Metformin fixed dose combination on reducing the risk of cardiovascular death in adults with type 2 diabetes mellitus and cardiovascular disease has not been established.

Dosage and Administration

Individualize starting dose based on the patient's current drug regimen.

- Take twice daily with meals, with gradual dose escalation to reduce the GI adverse effects due to Metformin. Adjust dosing based on effectiveness and tolerability while not exceeding the maximum recommended daily dose of Metformin Hydrochloride 2000 mg and Empagliflozin 25 mg.
- Switching to Jardimet®
  - *Patients on Metformin:* Switch to tablet containing Empagliflozin 5 mg with a similar total daily dose (TDD) of metformin.
  - *Patients on Empagliflozin:* Switch to tablet containing Metformin 500 mg with a similar TDD of Empagliflozin.
  - *Patients already treated with Empagliflozin and Metformin:* Switch to tablet containing the same total daily doses of each component.

Contraindications

It is contraindicated in patients with moderate to severe renal impairment (eGFR less than 45 mL/min/1.73 m^2), end stage renal disease, or dialysis.

Acute or chronic metabolic acidosis, including diabetic ketoacidosis or type 1 diabetes millitus. Diabetic ketoacidosis should be treated with insulin.

History of serious hypersensitivity reaction to Empagliflozin and Metformin Hydrochloride.

Warning and Precautions

Lactic Acidosis: Postmarketing cases of Metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. If Metformin-associated lactic acidosis is suspected, general supportive measures should be instituted promptly in a hospital setting, along with immediate discontinuation of Jardimet®.

Hypotension: Before initiating Jardimet® assess and correct volume status in patients with renal impairment, the elderly, in patients with low systolic blood pressure, and in patients on diuretics. Monitor for signs and symptoms during therapy.

Ketoacidosis: Assess patients who present with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level. If suspected, discontinue Jardimet®, evaluate and treat promptly. Before initiating Jardimet®, consider risk factors for ketoacidosis. Patients on Jardimet® may require monitoring and temporary discontinuation of therapy in clinical situations known to predispose to ketoacidosis.

Acute Kidney Injury and Impairment in Renal Function: Consider temporarily discontinuing in settings of reduced oral intake or fluid losses. If acute kidney injury occurs, discontinue and promptly treat. Monitor renal function during therapy.

Hypoglycemia: Consider lowering the dose of insulin secretagogue or insulin to reduce the risk of hypoglycemia when initiating Jardimet®.

Adverse Effects

Adverse effects of Jardimet® may include low blood sugar (hypoglycemia), urinary tract infection, increased urination, genital yeast infections, diarrhea, nausea, vomiting, gas, abdominal discomfort, indigestion, weakness or lack of energy, high cholesterol, joint pain, and headache.

Overdose

Overdose of Metformin Hydrochloride has occurred, including ingestion of amounts greater than 50 grams. Hypoglycemia was reported in approximately 10% of cases, but no causal association with Metformin has been established. Lactic acidosis has been reported in approximately 32% of Metformin overdose cases.

Metformin is dialyzable with a clearance of up to 170 mL/min under good hemodynamic conditions. Therefore, hemodialysis may be useful partly for removal of accumulated Metformin from patients in whom Jardimet® overdosage is suspected.

Use in Specific Populations

Pregnancy

Based on animal data showing adverse renal effects, Jardimet® is not recommended during the second and third trimesters of pregnancy.

Lactation

It is not known if Empagliflozin is excreted in human milk, and so is not recommended during breastfeeding.

Drug Interactions

Drug Interactions with Empagliflozin:

Diuretics

Co-administration of Empagliflozin with diuretics resulted in increased urine volume and frequency of voids, which might enhance the potential for volume depletion.

Insulin or Insulin Secretagogues

Co-administration of Empagliflozin with insulin or insulin secretagogues increases the risk for hypoglycemia.

Positive Urine Glucose Test

Monitoring glycemic control with urine glucose tests is not recommended in patients taking SGLT2 inhibitors as SGLT2 inhibitors increase urinary glucose excretion and will lead to positive urine glucose tests. Use alternative methods to monitor glycemic control.

Drug Interactions with Metformin Hydrochloride:

Drugs that Reduce Metformin Clearance

Concomitant use of drugs that interfere with common renal tubular transport systems involved in the renal elimination of Metformin (e.g., organic cationic transporter-2 [OCT2] / multidrug and toxin extrusion [MATE] inhibitors such as ranolazine, vandetanib, dolutegravir, and cimetidine) could increase systemic exposure to Metformin and may increase the risk for lactic acidosis. Consider the benefits and risks of concomitant use.

Carbonic Anhydrase Inhibitors

Topiramate or other carbonic anhydrase inhibitors (e.g., zonisamide, acetazolamide or dichlorphenamide) frequently causes a decrease in serum bicarbonate and induce non-anion gap, hyperchloremic metabolic acidosis. Concomitant use of these drugs may increase the risk of lactic acidosis. Consider more frequent monitoring of these patients.

Drugs Affecting Glycemic Control

Certain drugs tend to produce hyperglycemia and may lead to loss of glycemic control. These drugs include the thiazides and other diuretics, corticosteroids, phenothiazine, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetic, calcium channel blocking drugs, and isoniazid. When such drugs are administered to a patient receiving Jardimet®, the patient should be closely observed to maintain adequate glycemic control. When such drugs are withdrawn from a patient receiving Jardimet®, the patient should be observed closely for hypoglycemia.

Alcohol

Alcohol is known to potentiate the effect of Metformin on lactate metabolism. Warn patients against excessive alcohol intake while receiving Jardimet®.

Pharmaceutical Precaution

Keep in a dry place, below 30° C. Protect from light and keep out of the reach of children.

Commercial Pack

Jardimet® 5/500 Tablet: Box containing 30 tablets in 3x10's blister strips. Each film coated tablet contains Empagliflozin INN 5 mg and Metformin Hydrochloride BP 500 mg.

BEXIMCO PHARMA

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