Limpa

Linagliptin INN & Empagliflozin INN

COMPOSITION

Limpa 5/10 Tablet: Each film coated tablet contains Linagliptin INN 5 mg & Empagliflozin INN 10 mg.

Limpa 5/25 Tablet: Each film coated tablet contains Linagliptin INN 5 mg & Empagliflozin INN 25 mg.

PHARMACOLOGY

Limpa combines 2 anti-hyperglycemic agents with complementary mechanisms of action to improve glycemic control in patients with type 2 diabetes: Linagliptin, a DPP-4 inhibitor and Empagliflozin, a SGLT2 inhibitor.

Linagliptin: Linagliptin is an inhibitor of DPP-4, an enzyme that degrades the incretin hormones, glucagon-like peptide-1(GLP-1) and glucose-dependent insulinotropic polypeptide (GIP). Thus, linagliptin increases the concentrations of active incretin hormones, stimulating the release of insulin in a glucose dependent manner and decreasing the levels of glucagon in the circulation. Incretin hormones are secreted at a low basal level throughout the day, and levels rise immediately after a meal.

Empagliflozin: SGLT2 is the predominant transporter responsible for reabsorption of glucose from the glomerular filtrate back into the circulation. Empagliflozin is an inhibitor of SGLT2. By inhibiting SGLT2, Empagliflozin reduces renal reabsorption of filtered glucose and lowers the renal threshold for glucose, thereby increasing urinary glucose excretion.

INDICATIONS

Limpa Tablet is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease.

DOSAGE & ADMINISTRATION

The recommended dose is **Limpa** 5/10 mg Tablet once daily in the morning taken orally with or without food. In patients tolerating **Limpa** 5/10, the dose may be increased to **Limpa** 5/25 mg Tablet once daily.

CONTRAINDICATIONS

Combination of Linagliptin & Empagliflozin is contraindicated in patients on dialysis. It is also contraindicated in patients with a history of hypersensitivity reaction to Linagliptin, such as anaphylaxis, angioedema, exfoliative skin conditions, urticaria, bronchial hyper reactivity, or a history of serious hypersensitivity reaction to Empagliflozin.

WARNING & PRECAUTIONS

Pancreatitis: If pancreatitis is suspected, promptly discontinue combination of Linagliptin & Empagliflozin; ***Heart Failure:*** Consider risks and benefits of Linagliptin & Empagliflozin in patients who have known risk factors for heart failure. Monitor the signs and symptoms; ***Hypotension:*** Before initiating combination of Linagliptin & Empagliflozin assess and correct volume status with renal impairment, the elderly, in patients with low systolic blood pressure, and patients on diuretics. Monitor for signs and symptoms during therapy; ***Ketoacidosis:*** Assess patients who have with signs and symptoms of metabolic acidosis for ketoacidosis. If suspected, discontinue this combination. ***Acute kidney injury and impairment in renal function:*** If acute kidney injury occurs, discontinue combination of Linagliptin & Empagliflozin and monitor renal function during therapy; ***Urosepsis and Pyelonephritis:*** Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated; ***Hypoglycemia:*** Consider lowering the dose of insulin secretagogue or insulin to reduce the risk of hypoglycemia. ***Genital Mycotic Infections:*** Monitor and treat as appropriate; ***Fournier's gangrene (rare infection):*** Healthcare professionals should assess patients for Fournier's gangrene if they present with the symptoms (tenderness, redness, or swelling of the genitals or the area from the genitals back to the rectum and have a fever above 100.4° F or a general feeling of being unwell). If suspected, start treatment immediately with broad-spectrum antibiotics and surgical debridement if necessary.

SIDE EFFECTS

The most common adverse reactions (≥5%) associated with combination of Linagliptin & Empagliflozin (5/10 mg, 5/25 mg) were urinary tract infections, nasopharyngitis, and upper respiratory tract infections.

USE IN SPECIFIC POPULATIONS

Pregnancy: Advise females of the potential risk to a fetus especially during the second and third trimesters. ***Lactation:*** Combination of Linagliptin & Empagliflozin is not recommended when breastfeeding. ***Pediatric Patients:*** Safety and effectiveness of Linagliptin & Empagliflozin combination tablet in pediatric patients have not been established. ***Geriatric Patients:*** Higher incidence of adverse reactions related to volume depletion and reduced renal function. ***Renal Impairment:*** Higher incidence of adverse reactions related to reduced renal function.

DRUG INTERACTIONS

Co-administration of Empagliflozin with diuretics resulted in increased urine volume and frequency of voids, which cause volume depletion.

Linagliptin or Empagliflozin in combination with an insulin secretagogue (e.g., Sulfonylurea) or insulin was associated with a higher rate of hypoglycemia compared with placebo in a clinical trial.

Rifampin decreased Linagliptin exposure & efficacy may be reduced when administered in combination with a strong P-gp or CYP3A4 inducer.

OVERDOSE

In the event of an overdose with Linagliptin & Empagliflozin combination tablet, contact the Poison Control Center. Removal of Empagliflozin by hemodialysis has not been studied, and removal of Linagliptin by hemodialysis or peritoneal dialysis is unlikely.

STORAGE

- Store below 30°C, keep in dry place & protect from light.
- Keep out of reach of children.

PACKING

Limpa 5/10 Tablet: Each box contains 30 tablets in alu-alu blister pack.

Limpa 5/25 Tablet: Each box contains 10 tablets in alu-alu blister pack.

Manufactured by:
ARISTOPHARMA LTD.
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