

Emlozin L[®] 10/5

Empagliflozin & Linagliptin

COMPOSITION :

Emlozin L[®] 10/5 Tablet: Each film coated tablet contains Empagliflozin INN 10 mg & Linagliptin INN 5 mg.

Pharmacology :

It combines two oral antihyperglycemic agents Empagliflozin and Linagliptin with complementary mechanism of action to improve glycemic control in patients with type-2 diabetes. Empagliflozin is an inhibitor of Sodium-Glucose Co-Transporter-2 (SGLT2). SGLT2 is the predominant transporter, responsible for the reabsorption of glucose from the kidney back into the circulation. By inhibiting SGLT2, Empagliflozin reduces renal reabsorption of filtered glucose and lowers the renal threshold for glucose and thereby increases urinary glucose excretion. Linagliptin is an inhibitor of DPP-4 (dipeptidyl peptidase-4), an enzyme that degrades the incretin hormones GLP-1 (glucagon like peptide-1) and GIP (glucose dependent insulinotropic polypeptide). Thus, Linagliptin increases the concentrations of active incretin hormones, stimulating the release of insulin from pancreatic beta (β) cells in a glucose-dependent manner and decreasing the secretion of glucagon from pancreatic alpha (α) cells in the circulation.

Indication :

The combination of Empagliflozin INN & Linagliptin INN is 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 Linagliptin is appropriate.
- To reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease.
- To reduce the risk of cardiovascular death plus hospitalization for heart failure in adults with heart failure & reduces ejection fraction.

Dosage & administration :

- The recommended dose of **Emlozin L[®]** is Empagliflozin 10 mg/Linagliptin 5mg once daily, taken in the morning, with or without food.
- Dose may be increased to Empagliflozin 25 mg/Linagliptin 5 mg once daily
- Assess renal function before initiating **Emlozin L[®]**. Do not initiate **Emlozin L[®]** if eGFR is below 30 mL/min/1.73 m²

Contraindications :

The combination (Empagliflozin and Linagliptin) is contradicted in patients with severe renal impairment, end-stage renal disease, or dialysis, and history of hypersensitivity reaction to both or either Linagliptin and Empagliflozin such as anaphylaxis, angioedema, exfoliative skin condition, urticarial, or bronchial hyper-reactivity.

Warnings & precautions :

- **Pancreatitis:** If Pancreatitis is suspected, promptly discontinue.
- **Hypotension:** Before initiating this medication 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.
- **Impairment in renal function:** Before initiation and during therapy with Empagliflozin and Linagliptin renal function should be monitored in a routine basis. If acute kidney injury occurs, discontinue and promptly treat.
- **Hypoglycemia:** Consider lowering the dose of insulin secretagogue or insulin to reduce the risk of hypoglycemia when initiating this medication
- **Genital mycotic infections:** Monitor and treat as appropriate.
- **Increased LDL-C:** Monitor and treat as appropriate.

Side Effects :

Urinary tract infection and female genital mycotic infections, Stuffy or runny nose, sore throat, cough, diarrhea, nasopharyngitis and hypoglycemia.

Pregnancy and lactation :

Pregnant women : The limited available data in pregnant women are not sufficient to determine a drug associated risk for major birth defects and miscarriage.

Lactation : It is not known whether Empagliflozin is secreted in human milk. As many drugs are excreted in human milk, caution should be exercised when this combination is administered to a nursing mother.

Geriatric use :

No **Emlozin L[®]** dosage change is recommended based on age. As aging can be associated with reduced renal function, Empagliflozin should be used with caution as age increases. Care should be taken in dose selection and should be based on careful and regular monitoring of renal function.

Pediatric use :

Safety and effectiveness of Empagliflozin and Linagliptin combination in pediatric patients under 18 years of age have not been established.

Drug interactions :

- **Diuretics:** Co-administration of Empagliflozin with diuretics results in increased urine volume and frequency of voids, which might enhance the potential for volume depletion.
- **Insulin secretagogue:** Co-administration of Empagliflozin with an insulin secretagogue (e.g., sulfonylurea) or insulin may require lower doses of the insulin secretagogue or insulin to reduce the risk of hypoglycemia.
- **Strong P-glycoprotein/CYP3A4 inducer:** The efficacy of Linagliptin may be reduced when administered in combination (e.g. with Rifampin). Use of alternative treatments is strongly recommended.

Overdose :

In the event of an overdose it is reasonable to employ the usual supportive measures e.g. remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring (including obtaining an electrocardiogram) and institute supportive therapy as indicated by the patient's clinical status. With single dose of up to 600mg of Linagliptin (equivalent to 120 times the recommended daily dose) there were no dose-related clinical adverse drug reactions. There were no reports of overdose during clinical development program for Empagliflozin. Removal of Empagliflozin by hemodialysis has not been studied.

Storage :

Store in a dry and cool place below 30°C temperature and keep away from light and moisture. Keep out of reach of children.

Packing :

Emlozin L[®] 10/5 Tablet : Each box contains 2 X 10's tablets in blister pack.



Manufactured by

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