

Emlidus®

Empagliflozin INN & Linagliptin INN

Description

Emlidus® is a combination of Empagliflozin, a sodium-glucose cotransporter-2 (SGLT-2) inhibitor & Linagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor.

Mode of action

Empagliflozin: Empagliflozin is an inhibitor of SGLT2. By inhibiting SGLT2, Empagliflozin reduces renal reabsorption of filtered glucose and lowers the renal threshold for glucose, and thereby increases urinary glucose excretion.

Linagliptin: Linagliptin is a dipeptidyl peptidase-4 (DPP-4) inhibitor, which exerts its action by slowing the inactivation of incretin hormones. Incretin hormone levels are increased in response to a meal. When blood glucose concentrations are normal or elevated, incretin hormones increase insulin synthesis and release insulin from pancreatic beta cells. Incretin hormones also lower glucagon secretion from pancreatic alpha cells, leading to reduced hepatic glucose production.

Pharmacokinetics

Empagliflozin:

Absorption: After oral administration, peak plasma concentrations of Empagliflozin are reached at 1.5 hours post-dose.

Distribution: The apparent steady-state volume of distribution is estimated to be 73.8 L and plasma protein binding is 86.2%.

Metabolism: Primary route of metabolism of Empagliflozin in human is glucuronidation by the uridine 5'-diphospho-glucuronosyltransferases UGT2B7, UGT1A3, UGT1A8, and UGT1A9. Systemic exposure of each metabolite is less than 10% of total drug-related material.

Elimination: Elimination half-life of Empagliflozin is estimated to be 12.4 hours.

Linagliptin:

Linagliptin is rapidly absorbed and the peak plasma concentrations occur between 1.5 hours. The absolute bioavailability is approximately 30%. (70 - 80%) is protein bound. It is not extensively metabolized, 90% of dose is excreted unchanged. It is eliminated via the feces 80% and urine 5%.

Composition

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

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

Indications

Emlidus® is indicated-

- As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
- In adults with type 2 diabetes who have known cardiovascular disease when both Empagliflozin & Linagliptin is appropriate & Empagliflozin is needed to reduce the risk of cardiovascular death

Dosage & administration

The recommended dose is **Emlidus® 10/5 mg tablet** once daily, taken in the morning, with or without food. Dose may be increased to **Emlidus® 25/5 mg tablet** once daily.

Contraindications

- Severe renal impairment, end-stage renal disease, or dialysis
- Hypersensitivity to Empagliflozin, Linagliptin, or any of the excipients in **Emlidus®**

Side effects

Side effects of **Emlidus®** may include low blood sugar (hypoglycemia), pancreatitis, urinary tract infection, increased urination, genital yeast infections, diarrhea, nausea, vomiting, weakness or lack of energy, high cholesterol, joint pain, and headache.

Use in pregnancy & lactation

Pregnancy: There are no adequate & well controlled studies in pregnant woman. Use during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: Emlidus is not recommended in lactation

Precautions

- **Pancreatitis:** If pancreatitis is suspected, promptly discontinue
- **Ketoacidosis:** If ketoacidosis suspected, discontinue, evaluate and treat promptly.
- **Volume Depletion:** Before initiating, assess volume status and renal function in patients with impaired renal function, elderly patients, or patients on loop diuretics. Monitor for signs and symptoms 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 when initiating

Drug interactions

Empagliflozin: Diuretics: Co-administration of Empagliflozin with diuretics (thiazide and loop diuretics) result may increase urine volume (dehydration & hypotension).

Insulin or Insulin Secretagogues: Co-administration of Empagliflozin with insulin or insulin secretagogues such as sulfonylureas may increase the risk of hypoglycemia.

Linagliptin: The efficacy of linagliptin may be reduced when administered in combination with P-glycoprotein/CYP3A4 inducer (Rifampin).

Over dosage

In the event of an overdose with **Emlidus®** contact with the nearest hospital. Employ the usual supportive measures (e.g. remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring and institute supportive treatment) as dictated by the patients clinical status.

Storage

Keep out of reach of children. Store in a dry place, below 25°C temperature and protected from light.

Packaging

Emlidus® 10/5 mg Tablet: Each carton contains 14X1 tablets in Alu-Alu blister pack.

Emlidus® 25/5 mg Tablet: Each carton contains 14X1 tablets in Alu-Alu blister pack.