LINAX E

LINAGLIPTIN & EMPAGLIFLOZIN

Compositions:
Linax E 5/10 Tablet: Each film coated tablet contains Linagliptin INN 5 mg and Empagliflozin INN 10 mg &Linax E 5/25 Tablet: Each film coated tablet contains Linagliptin INN 5 mg and Empagliflozin INN 25 mg.

Pharmacology:
Linax E tablet is a combination of two oral antihyperglycemic drugs with complimentary mechanism of action to improve glycemic control in patients with type-2 diabetes mellitus: Linagliptin and Empagliflozin. 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. GLP-1 and GIP increase insulin biosynthesis and secretion from pancreatic beta cells in the presence of normal and elevated blood glucose levels. Furthermore, GLP-1 also reduces glucagon secretion from pancreatic alpha cells, resulting in a reduction in hepatic glucose output. Empagliflozin is a sodium-glucose co-transporter 2 (SGLT2) inhibitor. By inhibiting SGLT2, Empagliflozin reduces renal reabsorption of filtered glucose and lowers the renal threshold for glucose, and thereby increases urinary glucose excretion.

Dosage And Administration:
Adults:The recommended dose is Linagliptin 5 mg / Empagliflozin 10 mg once daily, taken in the morning, with or without food. Dose may be increased to Linagliptin 5 mg / Empagliflozin 25 mg once daily. Geriatric Patients: Empagliflozin is associated with osmotic diuresis, which could affect hydration status of patients age 75 years and older. No overall differences in safety or effectiveness of Linagliptin were observed between geriatric patients and younger adult patients. Renal Impairment: Linagliptin and Empagliflozin combination is not recommended for use in patients with an eGFR less than 30 mL/min/1.73 m².

Contraindications:
Patients on dialysis• Hypersensitivity to Linagliptin, Empagliflozin or any component of this product.

Warning And Precaution:
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.

Side Effects:
The most common adverse reactions associated with Linagliptin and Empagliflozin combination (a 5% or greater incidence) were urinary tract infections, nasopharyngitis, and upper respiratory tract infections.

Use in Pregnancy and Lactation:
Pregnancy: Linagliptin and Empagliflozin combination is not recommended during the

second and third trimesters of pregnancy. The limited available data in pregnant women are not sufficient to determine a drug-associated risk for major birth defects and miscarriage. There are risks to the mother and fetus associated with poorly controlled diabetes in pregnancy. Lactation: Linagliptin and Empagliflozin is not recommended while breastfeeding.

Drug Interaction:
Drug Interactions with Linagliptin: Inducers of P-glycoprotein or CYP3A4 Enzymes: Rifampin decreased Linagliptin exposure, suggesting that the efficacy of Linagliptin may be reduced when administered in combination with a strong P-gp or CYP3A4 inducer. Therefore, use of alternative treatments is strongly recommended when Linagliptin is to be administered with a strong P-gp or CYP3A4 inducer. Drug Interaction with Empagliflozin: Diuretics: Coadministration 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: Coadministration 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.

Overdosage:
In the event of an overdose with Linagliptin and Empagliflozin combination, contact the Poison Control Center. 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 patient’s clinical status. Removal of Empagliflozin by hemodialysis has not been studied, and removal of Linagliptin by hemodialysis or peritoneal dialysis is unlikely.

Storage:
Store in a cool (below 30° C) and dry place protected from light and moisture. Keep out of the reach of children.

Packing:
Linax E 5/10 Tablet: Each box contains 3x10 tablets in Alu-Alu Blister pack.Linax E 5/25 Tablet: Each box contains 2x10 tablets in Alu-Alu Blister pack.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.