

Elipta

Linagliptin INN &
Empagliflozin INN

Composition

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

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

Pharmacology

Linagliptin inhibits DPP-4 enzyme which declines the incretin hormones glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP). Linagliptin increases the concentrations of active incretin hormones, stimulating the release of insulin in a glucose-dependent manner and decreasing the levels of glucagon. Both incretin hormones are involved in the physiological regulation of glucose homeostasis. Incretin hormones are secreted at a low basal level throughout the day and levels rise immediately after meal intake. 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 an inhibitor of Sodium-glucose co-transporter 2 (SGLT2). SGLT2 is the predominant transporter responsible for reabsorption of glucose from 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.

Indication

Linagliptin & Empagliflozin combination indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Dosage & Administration

The recommended dose is Linagliptin & Empagliflozin 5/10 mg once daily in the morning, taken with or without food. Dose may be increased to Linagliptin & Empagliflozin 5/10 mg once daily for additional glycemic control.

Contraindications

Hypersensitivity to Linagliptin & Empagliflozin, or any of the excipients in Linagliptin & Empagliflozin, reactions such as anaphylaxis, angioedema, exfoliative skin conditions, urticaria, or bronchial hyperreactivity have occurred. Patients on dialysis.

Warnings and Precaution

• **Pancreatitis:** Acute pancreatitis, including fatal pancreatitis, has been reported in patients treated with Linagliptin. • **Ketoacidosis:** Reports of ketoacidosis, a serious life-threatening condition requiring urgent hospitalization have been identified in clinical trials and postmarketing surveillance in patients with type 1 and type 2 diabetes mellitus receiving sodium glucose co-transporter-2 (SGLT2) inhibitors, including Empagliflozin. Fatal cases of ketoacidosis have been reported in patients taking Empagliflozin. • **Volume Depletion:** Empagliflozin can cause intravascular volume depletion which may sometimes manifest as symptomatic hypotension or acute transient changes in creatinine. • **Urosepsis and Pyelonephritis:** There have been postmarketing reports of serious urinary tract infections including urosepsis and pyelonephritis requiring hospitalization in patients receiving SGLT2 inhibitors, including Empagliflozin. Treatment with SGLT2 inhibitors increases the risk for urinary tract infections. • **Hypoglycemia with Concomitant Use with Insulin & Insulin Secretagogues:** Insulin and insulin secretagogues are known to cause hypoglycemia. • **Necrotizing Fasciitis of the Perineum (Fournier's Gangrene):** Reports of necrotizing fasciitis of the perineum (Fournier's gangrene), a rare but serious and life-threatening necrotizing infection requiring urgent surgical intervention, have been identified in postmarketing surveillance in patients with diabetes mellitus receiving SGLT2 inhibitors, including Empagliflozin. • **Genital Mycotic Infections:** Empagliflozin increases the risk for genital mycotic infections. • **Hypersensitivity Reactions** • **Severe and Disabling Arthralgia Bullous Pemphigoid** • **Heart Failure:** An association between DPP-4 inhibitor treatment and heart failure has been observed in cardiovascular outcomes trials for two other members of the DPP-4 inhibitor class. These trials evaluated patients with type 2 diabetes mellitus and atherosclerotic cardiovascular disease.

Adverse Effects

The following important adverse reactions are described below and elsewhere in the labeling: • **Pancreatitis** • **Ketoacidosis** • **Volume Depletion** • **Urosepsis and Pyelonephritis** • **Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues** • **Necrotizing Fasciitis of the Perineum (Fournier's Gangrene)** • **Genital Mycotic Infections** • **Hypersensitivity Reactions** • **Severe and Disabling Arthralgia** • **Bullous Pemphigoid** • **Heart Failure.**

Interactions

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:** Linagliptin & 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. **Positive Urine Glucose Test:** SGLT2 inhibitors increase urinary glucose excretion and will lead to positive urine glucose tests. **Interference with 1,5-anhydroglucitol (1,5-AG) Assay:** Measurements of 1,5-AG are unreliable in assessing glycemic control in patients taking SGLT2 inhibitors. **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.

Use in Pregnancy & Lactation

Advise females of the potential risk to a fetus especially during the second and third trimesters. Linagliptin & Empagliflozin is not recommended when breastfeeding.

Overdosage

In the event of an overdose with Linagliptin & Empagliflozin, employ the usual supportive measures as dictated by the patient's clinical status. Removal of Linagliptin & Empagliflozin by hemodialysis has not been studied.

Storage

Do not store above 25°C. Protect from light. Keep out of the reach of children.

Packaging:

Elipta 5/10 Tablet: Each box contains 3X10's tablets in blister pack.

Elipta 5/25 Tablet: Each box contains 2X10's tablets in blister pack.

Manufactured by



Ziska Pharmaceuticals Ltd.
Kaliakoir, Gazipur, Bangladesh