Emjenta

Empagliflozin INN & Linagliptin INN

COMPOSITION

Emjenta 10/5 Tablet: Each film coated tablet contains Empagliflozin INN 10 mg and Linagliptin INN 5 mg.
Emjenta 25/5 Tablet: Each film coated tablet contains Empagliflozin INN 25 mg and Linagliptin INN 5 mg.

PHARMACOLOGY

Emjenta is a combination of Empagliflozin and Linagliptin. Empagliflozin is a sodium-glucose co-transporter 2 (SGLT-2) inhibitor and Linagliptin is a dipeptidyl peptidase-4 (DPP-4) inhibitor.
Sodium-glucose co-transporter 2 (SGLT-2) an important transporter responsible for reabsorption of glucose from the glomerular filtrate back into the blood circulation. Empagliflozin is an inhibitor of SGLT-2. By inhibiting SGLT-2, 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. DPP-4 is an enzyme that disrupt the incretin hormones glucagon-like peptide-1(GLP-1) and glucose-dependent insulinotropic polypeptide (GIP). So, 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. Both incretin hormones are involved in the physiological regulation of glucose homeostasis.

INDICATIONS

This combination 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.

Limitations of Use:

- Not for treatment of type 1 diabetes mellitus.
- It has not been studied in patients with pancreatitis.
- Not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR less than 30 mL/min/1.73 m^2.

DOSAGE AND ADMINISTRATION

The recommended dose is 10 mg Empagliflozin / 5 mg Linagliptin (Emjenta 10/5) once daily, taken in the morning, with or without food; Dose may be increased to 25 mg Empagliflozin / 5 mg Linagliptin (Emjenta 25/5) once daily.

Missed Dose:
If a dose is missed, it should be taken as soon as the patient remembers and patients are advised not to double their next dose.

CONTRAINDICATIONS

It is contraindicated in patients on dialysis. It is also contraindicated in the patients with a history of hypersensitivity to Empagliflozin and Linagliptin or any of the excipients in it.

WARNINGS AND PRECAUTIONS

Pancreatitis: There have been reports of acute pancreatitis, including fatal pancreatitis. If pancreatitis is suspected, promptly discontinue it.

Ketoacidosis: Assess patients who present with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level. If suspected, discontinue it and treat promptly. Before initiating it, consider risk factors for ketoacidosis.

Volume Depletion: Before initiating it, 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 it.

Necrotizing Fasciitis of the Perineum (Fournier's Gangrene): Serious, life-threatening cases have occurred in both females and males. Assess patients presenting with pain or tenderness, erythema or swelling in the genital or perineal area, along with fever or malaise; If suspected, institute prompt treatment.

Genital Mycotic Infections: Monitor and treat as appropriate.

Hypersensitivity Reactions: If hypersensitivity reactions occur, discontinue it, treat promptly; monitor until signs and symptoms resolve.

Arthralgia: Severe and disabling arthralgia has been reported in patients taking DPP-4 inhibitors. Consider as a possible cause for severe joint pain and discontinue drug if appropriate.

Bullous Pemphigoid: There have been reports of bullous pemphigoid requiring hospitalization. If bullous pemphigoid is suspected, discontinue it.

Heart Failure: Heart failure has been observed with two other members of the DPP-4 inhibitor class. Consider risks and benefits of it in patients who have known risk factors for heart failure.

SIDE EFFECTS

The most common side effects (5% or greater incidence) are urinary tract infections, nasopharyngitis and upper respiratory tract infection.

USE IN PREGNANCY & LACTATION

Pregnancy: Advise females of the potential risk to a fetus especially during the second and third trimesters.
Lactation: It is not recommended when breastfeeding.

USE IN CHILDREN

Safety and effectiveness of it in paediatric patients have not been established.

DRUG INTERACTIONS

Coadministration of Empagliflozin with diuretics resulted in increased urine volume and frequency of voids, which might enhance the potential for volume depletion. Empagliflozin or Linagliptin 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, decreases Linagliptin exposure. So, suggesting that the efficacy of Linagliptin may be reduced when administered in combination with a strong P-gp or CYP3A 4 inducer.

OVERDOSAGE

In the event of an overdose immediately contact with doctor. 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 temperature in a dry place. Protect from light & moisture. Keep out of the reach of children.

HOW SUPPLIED

Emjenta 10/5 Tablet: Each box contains 20 tablets in Alu-Alu blister pack.
Emjenta 25/5 Tablet: Each box contains 10 tablets in Alu-Alu blister pack.

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NIPRO JMI Pharma

Manufactured by:
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