Glympa®

Empagliflozin & Linagliptin

COMPOSITION

Glympa® 10/5 Tablet: Each film coated tablet contains Empagliflozin INN 10 mg & Linagliptin INN 5 mg. **Glympa® 25/5** Tablet: Each film coated tablet contains Empagliflozin INN 25 mg & Linagliptin INN 5 mg.

PHARMACOLOGY

Glympa® combines 2 antihyperglycemic agents with complementary mechanisms of action to improve glycemic control in patients with type 2 diabetes: Empagliflozin, a sodium-glucose co-transporter (SGLT2) inhibitor and Linagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor. By inhibiting SGLT2, Empagliflozin reduces renal reabsorption of filtered glucose and lowers the renal threshold for glucose, and thereby increases urinary glucose excretion. Linagliptin, a DPP-4 inhibitor increases the concentrations of active incretin hormones (GLP-1 and GIP), 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.

INDICATION

Glympa® is indicated

• As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus

• To reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease

Limitations of use:

• Not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis

• Has not been studied in patients with a history of 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 Empagliflozin 10 mg/Linagliptin 5 mg (**Glympa®** 10/5) once daily, taken in the morning, with or without food. Dose may be increased to Empagliflozin 25 mg/Linagliptin 5 mg (**Glympa®** 25/5) once daily.

SIDE EFFECT

The most common side effects of Empagliflozin & Linagliptin include urinary tract infection, stuffy or runny nose and sore throat, upper respiratory tract infection. Besides, Low blood sugar (hypoglycemia), necrotizing fasciitis of the perineum, vaginal yeast infection, yeast infection of the penis, joint pain, skin reaction, heart failure etc. can happen.

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.

CONTRAINDICATION

Patient on dialysis

Hypersensitivity to Empagliflozin, Linagliptin, or any of the excipients

DRUG INTERACTION

Empagliflozin: Diuretics: Co-administration of Empagliflozin with diuretics resulted in increased urine volume. Insulin or Insulin Secretagogues: Co-administration 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.

Linagliptin: P-glycoprotein or CYP3A4 inducer: 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.

USE IN PREGNANCY AND LACTATION

Pregnancy: Empagliflozin or Empagliflozin & Linagliptin 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: There is no information regarding the presence of Empagliflozin & Linagliptin, or its individual components in human milk, the effects on the breastfed infant, or the effects on milk production. Use is not recommended while breastfeeding.

PEDIATRIC USE

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

GERIATRIC USE

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

Empagliflozin: The glucose lowering benefit of empagliflozin 25 mg decreased in patients with worsening renal function. Efficacy and safety studies with Empagliflozin did not enroll patients with ESRD on dialysis or patients with an eGFR less than 30 mL/min/1.73 m^2.

HEPATIC IMPAIRMENT

Can be used in patients with hepatic impairment.

STORAGE CONDITION

Store below 25°C in dry place. Keep away from light. Keep out of reach of children.

HOW SUPPLIED

Glympa® 10/5 Tablet: Each box contains 20 / 30 / 50 tablets in Blister pack.

Glympa® 25/5 Tablet: Each box contains 10 / 20 / 30 / 50 tablets in Blister pack.

SQUARE