Generic Name:
Empagliflozin/linagliptin
Trade Name:
Glyxambi
Company:
Boehringer Ingelheim and Eli Lilly
Notes:

FDA has approved first-in-class empagliflozin/linagliptin tablets as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes when both empagliflozin and linagliptin are appropriate treatments.

It is the first and only diabetes treatment in the United States to combine the dual mechanisms of action of a sodium?glucose cotransporter-2 (SGLT-2) inhibitor and a dipeptidyl peptidase-4 (DPP-4) inhibitor in a once-daily tablet taken in the morning.

Approval was based on a Phase III clinical trial that evaluated the efficacy and safety of empagliflozin/linagliptin (10/5 mg and 25/5 mg) compared with the individual components of empagliflozin (10 mg or 25 mg) or linagliptin (5 mg) in adults with type 2 diabetes who were also taking high-dose metformin (mean dose 1,889 mg daily). The study randomized 686 adults with type 2 diabetes and hemoglobin glycosylated hemogoblin (A1C) between 7.0% and 10.5% to examine the change from baseline in A1C at 24 weeks.

As an add-on to metformin, empagliflozin/linagliptin showed statistically significant reductions in A1C compared with empagliflozin and linagliptin alone at 24 weeks. Although not approved for lowering weight, the combination drug provided significant weight loss at 24 weeks compared with linagliptin alone.

Empagliflozin/linagliptin is not recommended in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

The most common adverse effects include urinary tract infections, stuffy or runny nose and sore throat, and upper respiratory tract infections.

Medication Monitor Categories:
New Drug Approvals