Generic Name:
Semaglutide
Trade Name:
Ozempic
Company:
Novo Nordisk
Notes:

Novo Nordisk announced FDA approval of semaglutide injection 0.5 mg or 1 mg, a once-weekly glucagon-like peptide (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes.

The agent is administered once weekly on the same day each week and can be taken any time of the day, with or without meals.

Approval was based on the results from a Phase IIIa clinical trial program comprising eight trials involving more than 8,000 adults with type 2 diabetes, including a 2-year cardiovascular outcomes trial that evaluated safety in adults with type 2 diabetes at high risk of cardiovascular events. Treatment with semaglutide showed clinically meaningful and statistically significant reductions in A1C compared with placebo, sitagliptin, and exenatide extended-release. As a secondary endpoint in the trials, treatment resulted in reductions in body weight.

The most common adverse reactions (≥5% of patients) are nausea, vomiting, diarrhea, abdominal pain, and constipation.

Novo Nordisk expects to launch the new drug in early 2018.

Medication Monitor Categories:
New Drug Approvals