



FDA Approves First Treatment to Reduce Risk of Serious Heart Problems Specifically in Adults with Obesity or Overweight

Weight-loss drug Wegovy (semaglutide) is now approved for cardiovascular risk reduction.

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Today, the U.S. Food and Drug Administration approved a new indication for use for Wegovy (semaglutide) injection to reduce the risk of cardiovascular death, heart attack and stroke in adults with cardiovascular disease and either obesity or overweight. Wegovy should be used in addition to a reduced calorie diet and increased physical activity. Cardiovascular disease is a group of diseases of the heart and blood vessels.

“Wegovy is now the first weight loss medication to also be approved to help prevent life-threatening cardiovascular events in adults with cardiovascular disease and either obesity or overweight,” said John Sharretts, MD, director of the Division of Diabetes, Lipid Disorders, and Obesity in the FDA’s Center for Drug Evaluation and Research. “This patient population has a higher risk of cardiovascular death, heart attack and stroke. Providing a treatment option that is proven to lower this cardiovascular risk is a major advance for public health.”

Obesity or overweight affect approximately 70% of American adults. Obesity and overweight are serious health issues that increase the risk for premature death and a variety of health problems, including heart attack and stroke.

Wegovy contains semaglutide, a glucagon-like peptide-1 (GLP-1) receptor agonist. Therefore, Wegovy should not be used in combination with other semaglutide-containing products or other GLP-1 receptor agonists.

Wegovy’s efficacy and safety for this new indication were studied in a multi-national, multi-center, placebo-controlled double-blind trial that randomly assigned over 17,600 participants to receive either Wegovy or placebo. Participants in both groups also received standard-of-care medical treatment (e.g., management of blood pressure and cholesterol) and healthy lifestyle counseling (including diet and physical activity). Wegovy significantly [reduced the risk of major adverse cardiovascular events](#) (cardiovascular death, heart attack and stroke), which occurred in 6.5% of

participants who received Wegovy compared to 8% of participants who received placebo.

The prescribing information for Wegovy contains a boxed warning to inform health care professionals and patients about the risk of thyroid C-cell tumors. Because of this risk, Wegovy should not be used in patients with a personal or family history of medullary thyroid carcinoma or in patients with a rare condition called Multiple Endocrine Neoplasia syndrome type 2.

Wegovy should not be used in patients with a history of a severe allergic reaction to semaglutide or to any of the other ingredients. Patients should stop Wegovy immediately and seek medical help if a severe allergic reaction is suspected.

Wegovy also contains warnings for inflammation of the pancreas (pancreatitis), gallbladder problems (including gallstones), low blood sugar, acute kidney injury, hypersensitivity reactions, diabetic retinopathy (damage to the eye's retina), increased heart rate and suicidal behavior or thinking. Patients should discuss with their health care provider if they have symptoms of pancreatitis or gallstones. If Wegovy is used with insulin or with a medication that causes insulin secretion, patients should speak to their health care provider about the risk of low blood sugar. Healthcare professionals should monitor patients for kidney disease, diabetic retinopathy and depression or suicidal behaviors or thoughts.

The most common side effects of Wegovy include nausea, diarrhea, vomiting, constipation, abdominal (stomach) pain, headache, fatigue, dyspepsia (indigestion), dizziness, abdominal distension, eructation (belching), hypoglycemia (low blood sugar) in patients with diabetes, flatulence (gas buildup) and gastroesophageal reflux disease (heartburn).

Wegovy received [Priority Review](#) designation for this indication.

The FDA granted the approval to Novo Nordisk A/S.

Wegovy is also approved to reduce excess weight and maintain weight reduction long term in certain adults with obesity or overweight and certain children with obesity, for use in addition to a reduced calorie diet and increased physical activity.

This [news release](#) was published by the Food and Drug Administration on March 8, 2024.