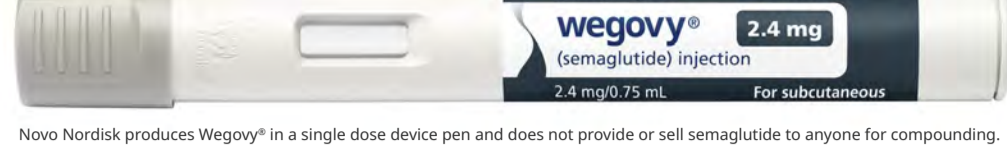


About Wegovy[®] (semaglutide) injection 2.4 mg

Wegovy[®] indications

The first-and-only medicine indicated for both reduction of the risk of major adverse cardiovascular events (MACE) such as death, heart attack, or stroke, and for long-term weight management.¹



Wegovy[®] is available in the following dose strengths: 0.25 mg, 0.5 mg, 1 mg, 1.7 mg and 2.4 mg.

Wegovy[®] 2.4 mg is indicated, along with a reduced calorie diet and increased physical activity¹:



to reduce the risk of major cardiovascular events such as death, heart attack, or stroke in adults with known heart disease and with either obesity or overweight.



that may help adults and children aged 12 years and older with obesity, or some adults with overweight who also have weight-related medical problems, to help them lose excess body weight and keep the weight off.

- Wegovy[®] contains semaglutide and should not be used with other semaglutide-containing products or other GLP-1 receptor agonist medicines.
- It is not known if Wegovy[®] is safe and effective for use in children under 12 years of age.

How Wegovy[®] works

Weight loss and weight maintenance

Your brain gets signals from different places in your body. Some of these signals are called appetite hormones that help regulate how much food you eat. Wegovy[®] works similarly to one of these natural appetite hormones, so you eat fewer calories, and lose weight.



Affects appetite



Reduces caloric intake



Lowers body weight

Cardiovascular (CV) Risk Reduction

The exact mechanism of CV risk reduction has not been established.

The most common side effects of Wegovy[®] may include: nausea, diarrhea, vomiting, constipation, stomach (abdomen) pain, headache, tiredness (fatigue), upset stomach, dizziness, feeling bloated, belching, low blood sugar in people with type 2 diabetes, gas, stomach flu, heartburn, and runny nose or sore throat.¹

Want to learn more about Wegovy[®]? Please click [here](#) for Prescribing Information and Medication Guide. Please click [here](#) for Important Safety Information or see below

STEP Phase 3a clinical program

Wegovy[®] has been studied across multiple phase 3 clinical trials that have formed the basis of its FDA-approved indications.

Semaglutide Treatment Effect in People with obesity (STEP) phase 3a pivotal clinical development program, which consisted of²⁻⁶:

- 4 Trials
- ~4,500 Adults 18 or older
- 392 Investigator sites
- 26 Countries

Wegovy[®] was also investigated in the STEP TEENS trial, which tested the safety and efficacy of Wegovy[®] in 201 people with obesity aged 12 to <18 years old.⁷



SELECT clinical trial

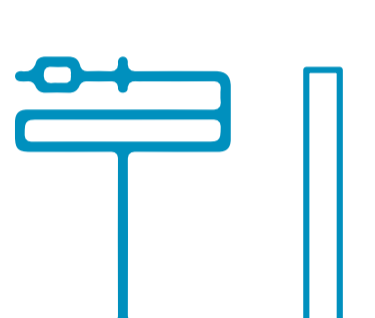
The Semaglutide Effects on Cardiovascular Outcomes in People with Overweight or Obesity (SELECT) trial was conducted in adults with established cardiovascular disease without diabetes⁸:

- 17,604 Adults
- 45+ Years old
- 800+ Investigator sites
- 41 Countries

STEP Trial designs

The primary endpoint for the STEP 1-4 trials was weight loss.

Patients who participated in the STEP phase 3a trials were randomized to receive either Wegovy[®] (plus a reduced calorie diet and increased physical activity) or placebo (plus a reduced calorie diet and increased physical activity) and evaluated over a 68-week period.³



- In the STEP 1-4 trials, weight loss was measured by percent change in body weight as a primary endpoint.³
- In the STEP 1-3 trials, the percent of patients who achieved $\geq 5\%$ reduction in body weight was also a primary endpoint.³
- In STEP TEENS, the primary endpoint was percent change in BMI.⁷

SELECT Trial design

The primary endpoint for the SELECT Trial was time to first occurrence of three-part composite MACE (cardiovascular death, non-fatal myocardial infarction [heart attack], or non-fatal stroke).⁸



Patients who participated in SELECT were randomized to receive either Wegovy[®] 2.4 mg or placebo, both in addition to CV standard of care, in⁸:

- A multicenter, double-blind, placebo-controlled, event-driven superiority trial.
- 8,803 received semaglutide; 8,801 received placebo.
- The mean duration of follow-up was ~40 months.
- CV standard of care included management of CV risk factors and individualized healthy lifestyle counseling (including diet and physical activity).

Key trial results from the Wegovy[®] clinical program*

The STEP 1 trial^{1-3,9}

Adults taking Wegovy[®] lost an average of ~35 lb

In a 68-week medical study of 1,961 adults** living with obesity or excess weight with a related medical problem:



PEOPLE TAKING PLACEBO IN THE STUDY (NOT ON MEDICINE) LOST AN AVERAGE OF 6 LB (OR ~2.5% BODY WEIGHT)

...some lost even more

In addition to a reduced calorie diet and increased physical activity, people in this study taking Wegovy[®] lost more weight vs placebo

- 83% of adults taking Wegovy[®] lost 5% or more weight, compared to 31% taking placebo
- 66% of adults taking Wegovy[®] lost 10% or more weight, compared to 12% taking placebo
- 48% of adults taking Wegovy[®] lost 15% or more weight, compared to 5% taking placebo

ABOUT 1 IN 3 ADULTS ACHIEVED 20% WEIGHT LOSS³

46^{LB}

CALCULATED FROM ~232LB STARTING WEIGHT

While taking Wegovy[®] people not only lost weight but also kept it off.

*Individual results may vary

**Results are from a 68-week medical study of adults with obesity (BMI ≥ 30) and adults with excess weight (BMI ≥ 27) who also had weight-related medical problems including high blood pressure or high cholesterol. People with type 2 diabetes were excluded. Both groups received instruction for a reduced-calorie meal plan and increased physical activity. 7% of people taking Wegovy[®] (92 people) left the medical study due to side effects, compared to 3.1% of people taking placebo (20 people).

30% of people taking Wegovy[®] lost 20% or more weight, compared to 2% of people taking placebo, in a supportive measure.

In medical studies, people who stopped taking Wegovy[®] generally regained weight.

The SELECT Cardiovascular Outcome (CVOT) Trial^{1,8,9}

Demonstrated that Wegovy[®] significantly reduced the risk of MACE in adults 45 and older with overweight or obesity and established CVD with no history of diabetes. The primary endpoint was time to first occurrence of a three-part composite MACE that included CV death, non-fatal myocardial infarction, or non-fatal stroke. Results apply to Wegovy[®] 2.4 mg vs placebo.

16% of people taking Wegovy[®] (1,461 people) left the medical study due to side effects, compared to 8% of people taking placebo (718 people).^{1,8}

MACE occurred in 6.5% of patients taking Wegovy[®] (569 patients of 8,803 on Wegovy[®]) vs 8.0% on placebo (701 of 8,801 on placebo), (HR 0.80 [95% CI: 0.72, 0.90], p<0.001)

20% relative risk reduction (RRR) (1.5% absolute risk reduction (ARR)⁹) in MACE with Wegovy[®] as evaluated in patients with overweight or obesity and established CVD without diabetes.

- Relative risk is a ratio of the probability of an event occurring in the exposed or intervention group versus the probability of the event occurring in the non-exposed or control group.¹⁰ Relative risk reduction (RRR) measures how much the treatment reduced the risk of adverse outcomes in an exposed group as compared to the control group.¹¹ In SELECT, the control group was defined as placebo and standard of care only, and the exposed group was defined as taking Wegovy[®] 2.4 mg plus standard of care.
- Absolute risk is the chance a patient has of developing the disease over a certain time.¹⁰ Absolute risk reduction (ARR) is the difference in absolute risk between the exposed or intervention group and a non-exposed or control group.¹¹

*1.5% ARR at 40 months (mean duration of follow-up).⁹

Data from the Wegovy[®] clinical trial program published in top peer-reviewed journals

STEP 1 The NEW ENGLAND JOURNAL of MEDICINE [Weight Management in Adults with Overweight or Obesity²](#)

STEP 2 THE LANCET [Weight Management in Adults with Overweight or Obesity, and Type 2 Diabetes⁴](#)

STEP 3 JAMA [Weight Management as an Adjunct to Intensive Behavioral Therapy in Adults with Overweight or Obesity⁵](#)

STEP 4 JAMA [Continued Weight Management vs Placebo on Weight Loss Maintenance in Adults with Overweight or Obesity⁶](#)

STEP TEENS The NEW ENGLAND JOURNAL of MEDICINE [Once-Weekly Semaglutide in Adolescents with Obesity⁷](#)

SELECT The NEW ENGLAND JOURNAL of MEDICINE [Semaglutide and Cardiovascular Outcomes in Obesity without Diabetes⁸](#)

Wegovy[®] Indication and Important Safety Information

What is Wegovy[®]?

WEGOVY[®] (semaglutide) injection 2.4 mg is an injectable, prescription medicine used with a reduced calorie diet and increased physical activity:

- to reduce the risk of major cardiovascular events such as death, heart attack, or stroke in adults with known heart disease and with either obesity or overweight.
- that may help adults and children aged 12 years and older with obesity, or some adults with overweight who also have weight-related medical problems, to help them lose excess body weight and keep the weight off.

Wegovy[®] contains semaglutide and should not be used with other semaglutide-containing products or other GLP-1 receptor agonist medicines.

It is not known if Wegovy[®] is safe and effective for use in children under 12 years of age.

Important Safety Information

What is the most important information I should know about Wegovy[®]?

Wegovy[®] may cause serious side effects, including:

- **possible thyroid tumors, including cancer.** Tell your healthcare provider if you get a lump or swelling in your neck, hoarseness, trouble swallowing, or shortness of breath. These may be symptoms of thyroid cancer. In studies with rodents, Wegovy[®] and medicines that work like Wegovy[®] caused thyroid tumors, including thyroid cancer. It is not known if Wegovy[®] will cause thyroid tumors or a type of thyroid cancer called medullary thyroid carcinoma (MTC) in people
- Do not use Wegovy[®] if you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC) or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
- **Do not use Wegovy[®] if:**
 - you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC) or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
 - you have had a serious allergic reaction to semaglutide or any of the ingredients in Wegovy[®]

Before using Wegovy[®], tell your healthcare provider if you have any other medical conditions, including if you:

- have or have had problems with your pancreas or kidneys
- have type 2 diabetes and a history of diabetic retinopathy
- have or have had depression, thoughts, or mental health issues
- are pregnant or plan to become pregnant. Wegovy[®] may harm your unborn baby. You should stop using Wegovy[®] 2 months before you plan to become pregnant
- are breastfeeding or plan to breastfeed. It is not known if Wegovy[®] passes into your breast milk

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Wegovy[®] may affect the way some medicines work and some medicines may affect the way Wegovy[®] works. Tell your healthcare provider if you are taking other medicines to treat diabetes, including sulfonylureas or insulin. Wegovy[®] slows stomach emptying and can affect medicines that need to pass through the stomach quickly.

What are the possible side effects of Wegovy[®]?

Wegovy[®] may cause serious side effects, including:

- **inflammation of your pancreas (pancreatitis).** Stop using Wegovy[®] and call your healthcare provider right away if you have severe pain in your stomach area (abdomen) that will not go away, with or without vomiting. You may feel the pain from your abdomen to your back
- **gallbladder problems.** Wegovy[®] may cause gallbladder problems, including gallstones. Some gallstones may need surgery. Call your healthcare provider if you have symptoms, such as pain in your upper stomach (abdomen), fever, yellowing of the skin or eyes (jaundice), or clay-colored stools
- **increased risk of low blood sugar (hypoglycemia), especially those who also take medicines for diabetes such as insulin or sulfonylureas.** This can be a serious side effect. Talk to your healthcare provider about how to recognize and treat low blood sugar and check your blood sugar before you start and while you take Wegovy[®]. Signs and symptoms of low blood sugar may include dizziness or light-headedness, blurred vision, anxiety, irritability or mood changes, sweating, slurred speech, hunger, confusion or drowsiness, shakiness, weakness, headache, fast heartbeat, or feeling jittery
- **kidney problems (kidney failure).** In people who have kidney problems, diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration), which may cause kidney problems to get worse. It is important for you to drink fluids to help reduce your chance of dehydration
- **serious allergic reactions.** Stop using Wegovy[®] and get medical help right away, if you have any symptoms of a serious allergic reaction, including swelling of your face, lips, tongue, or throat; problems breathing or swallowing; severe rash or itching; fainting or feeling dizzy; or very rapid heartbeat
- **change in vision in people with type 2 diabetes.** Tell your healthcare provider if you have changes in vision during treatment with Wegovy[®]
- **increased heart rate.** Wegovy[®] can increase your heart rate while you are at rest. Tell your healthcare provider if you feel your heart racing or pounding in your chest and it lasts for several minutes
- **depression or thoughts of suicide.** You should pay attention to any mental changes, especially sudden changes in your mood, behaviors, thoughts, or feelings. Call your healthcare provider right away if you have any mental changes that are new, worse, or worry you

The most common side effects of Wegovy[®] may include: nausea, diarrhea, vomiting, constipation, stomach (abdomen) pain, headache, tiredness (fatigue), upset stomach, dizziness, feeling bloated, belching, low blood sugar in people with type 2 diabetes, gas, stomach flu, heartburn, and runny nose or sore throat.

References

1. Wegovy[®] (semaglutide) injection 2.4 mg Prescribing Information. Plainsboro, NJ: Novo Nordisk Inc. March 2024.
2. Wilding JP, Batterham R, Davies S, et al. Once-weekly semaglutide in adults with overweight or obesity. *N Engl J Med.* 2021;384:989-1002. doi:10.1056/NEJMoa2032183.
3. Kushner RF, Caronna S, Davies M, et al. Semaglutide 2.4 mg for the treatment of obesity: Key elements of the STEP Trials 1 to 5. *Obesity.* 2020;28:1050-1061.
4. Davies M, Færch L, Jeppesen OK, et al. Semaglutide 2.4 mg once a week in adults with overweight or obesity, and type 2 diabetes. *Lancet.* 2021;397(10278):971-984. doi:10.1016/S0140-6736(21)00213-0.
5. Wadden TA, Bailey TS, Billings LK, et al. Effect of subcutaneous semaglutide vs placebo as an adjunct to intensive behavioral therapy on body weight in adults with overweight or obesity: The STEP 3 randomized clinical trial. *JAMA.* 2021;325(14):1403-1413. doi:10.1001/jama.2021.1831.
6. Rubino D, Abrahamson N, Davies M, et al. Effect of continued weekly subcutaneous semaglutide vs placebo on weight loss maintenance in adults with overweight or obesity: The STEP 4 randomized clinical trial. *JAMA.* 2021;325(14):1414-1425. doi:10.1001/jama.2021.3224.
7. Weghuber D, Barrett T, Barrientos-Pérez M, et al. Once-weekly semaglutide in adolescents with obesity. *N Engl J Med.* 2022;387: 2245-2257.
8. Linnoff M, Brown-Frandsen K, Colhoun H, et al. Semaglutide and cardiovascular outcomes in obesity without diabetes. *N Engl J Med.* 2023;389: 2221-2232.
9. Data on File. Novo Nordisk, Inc.
10. Tenney S, Hoffman MR. Relative Risk. *StatPearls.* 2023.
11. Irwig L, Irwig J, Tevessa L, et al. Relative risk, relative and absolute risk reduction, number needed to treat and confidence intervals. *Smart Health Choices: Making Sense of Health Advice.* 2008.