

In combination with a reduced calorie diet and increased physical activity, Wegovy® (semaglutide) injection 2.4 mg is indicated for the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults.

The indication for MASH is approved under accelerated approval based on improvement of MASH and fibrosis. Continued approval for this indication may be contingent upon the verification and description of clinical benefit in a confirmatory trial.

In combination with a reduced calorie diet and increased physical activity,

Wegovy® is NOW APPROVED

for the treatment of noncirrhotic **MASH**, formerly known as NASH, with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults¹

Learn about this new indication
now at [WEGOVYPRO.com/MASH](https://www.wegovipro.com/MASH)



Actor portrayals.

Indication and Usage

- Wegovy® (semaglutide) injection 2.4 mg is indicated in combination with a reduced calorie diet and increased physical activity for the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults.

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Limitations of Use:

Wegovy® contains semaglutide. Coadministration with other semaglutide-containing products or with any GLP-1 receptor agonist is not recommended

Important Safety Information

WARNING: RISK OF THYROID C-CELL TUMORS

- In rodents, semaglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Wegovy® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined
- Wegovy® is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Wegovy® and inform them of symptoms of thyroid tumors (e.g. a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Wegovy®

Contraindications

- Wegovy® is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2, and in patients with a prior serious hypersensitivity reaction to semaglutide or to any of the excipients in Wegovy®. Serious hypersensitivity reactions, including anaphylaxis and angioedema have been reported with Wegovy®

Warnings and Precautions

- **Risk of Thyroid C-Cell Tumors:** Patients should be further evaluated if serum calcitonin is measured and found to be elevated or thyroid nodules are noted on physical examination or neck imaging
- **Acute Pancreatitis:** Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with GLP-1 receptor agonists, including Wegovy®. Observe patients carefully for signs and symptoms of acute pancreatitis, which may include persistent severe abdominal pain (sometimes radiating to the back), nausea, or vomiting. If acute pancreatitis is suspected, discontinue Wegovy® and initiate appropriate management
- **Acute Gallbladder Disease:** Treatment with Wegovy® is associated with an increased occurrence of cholelithiasis and cholecystitis. The incidence of cholelithiasis and cholecystitis was higher in Wegovy® pediatric patients aged 12 years and older than in Wegovy® adults. In clinical trials in adult patients for weight reduction, cholelithiasis was reported by 1.6% of Wegovy® patients and 0.7% of placebo patients. Cholecystitis was reported by 0.6% of Wegovy® patients and 0.2% of placebo patients. In a clinical trial in pediatric patients aged 12 years and older for weight reduction, cholelithiasis was reported by 3.8% of Wegovy® patients and 0% placebo patients. Cholecystitis was reported by 0.8% of Wegovy® pediatric patients and 0% placebo patients. Substantial or rapid weight loss can increase the risk of cholelithiasis; however, the incidence of acute gallbladder disease was greater in Wegovy® patients than in placebo patients, even after accounting for the degree of weight loss. If cholelithiasis is suspected, gallbladder studies and appropriate clinical follow-up are indicated
- **Hypoglycemia:** Wegovy® lowers blood glucose and can cause hypoglycemia. In a trial of adult patients with type 2 diabetes for weight reduction, hypoglycemia was reported in 6.2% of Wegovy® patients versus 2.5% of placebo patients. Patients with diabetes taking Wegovy® with an insulin or insulin secretagogue (e.g. sulfonylurea) may have an increased risk of hypoglycemia, including severe hypoglycemia. The use of Wegovy® in patients with type 1 diabetes or in combination with insulin has not been evaluated. Inform patients of the risk of hypoglycemia and educate them on the signs and symptoms. Monitor blood glucose in patients with diabetes

Please see Important Safety Information throughout.
Please [click here](#) for Prescribing Information, including Boxed Warning.

ONCE-WEEKLY

wegovy®
semaglutide injection **2.4 mg**

Wegovy® (semaglutide) dosing for adults with Noncirrhotic MASH with Moderate to Advanced Liver Fibrosis

Dose-escalation schedule for adults with MASH

Start your patients with once-weekly Wegovy® at 0.25 mg and escalate the dose every 4 weeks¹



The recommended maintenance dosage of Wegovy® for the treatment of noncirrhotic MASH with moderate to advanced liver fibrosis is 2.4 mg injected subcutaneously once weekly.¹

If patients do not tolerate the maintenance dosage of 2.4 mg once weekly, the dosage can be decreased to 1.7 mg once weekly. Consider reescalation to 2.4 mg once weekly.¹

Follow the recommended dosage initiation and escalation schedule to reduce the risk of gastrointestinal adverse reactions.¹

- If patients do not tolerate a dose during dose escalation, consider delaying dose escalation for 4 weeks¹
 - If 1 dose is missed and the next scheduled dose is more than 2 days away (48 hours), administer Wegovy® as soon as possible. If 1 dose is missed and the next scheduled dose is less than 2 days away (48 hours), do not administer the dose. Resume dosing on the regularly scheduled day of the week¹
 - If 2 or more consecutive doses are missed, resume dosing as scheduled or, if needed, reinstate Wegovy® and follow the dose-escalation schedule, which may reduce the occurrence of gastrointestinal symptoms associated with reinstitution of treatment¹
- Injected subcutaneously once weekly.¹

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

- **Acute Kidney Injury Due to Volume Depletion:** There have been postmarketing reports of acute kidney injury, in some cases requiring hemodialysis, in patients treated with semaglutide. The majority of the reported events occurred in patients who experienced gastrointestinal reactions leading to dehydration such as nausea, vomiting, or diarrhea. Monitor renal function in patients reporting adverse reactions to Wegovy® that could lead to volume depletion, especially during initiation and escalation of Wegovy®
- **Severe Gastrointestinal Adverse Reactions:** Use of Wegovy® has been associated with gastrointestinal adverse reactions, sometimes severe. In clinical trials in adults for weight reduction, severe gastrointestinal adverse reactions were reported more frequently among patients receiving Wegovy® (4.1%) than placebo (0.9%). Wegovy® is not recommended in patients with severe gastroparesis
- **Hypersensitivity Reactions:** Serious hypersensitivity reactions (e.g., anaphylaxis, angioedema) have been reported with Wegovy®. If hypersensitivity reactions occur, discontinue use of Wegovy®, treat promptly per standard of care, and monitor until signs and symptoms resolve. Use caution in a patient with a history of anaphylaxis or angioedema with another GLP-1 receptor agonist
- **Diabetic Retinopathy Complications in Patients with Type 2 Diabetes:** In a trial of adult patients with type 2 diabetes and BMI greater than or equal to 27 kg/m² for weight reduction, diabetic retinopathy was reported by 4.0% of Wegovy® patients and 2.7% of placebo patients. Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy
- **Heart Rate Increase:** Mean increases in resting heart rate of 1 to 4 beats per minute (bpm) were observed in Wegovy® adult patients compared to placebo in weight reduction clinical trials. More Wegovy® adult patients compared with placebo had maximum changes from baseline of 10 to 19 bpm (41% versus 34%) and 20 bpm or more (26% versus 16%). In a clinical trial for weight reduction in pediatric patients aged 12 years and older with normal baseline heart rate, more patients treated with Wegovy® compared to placebo had maximum changes in heart rate of 20 bpm or more (54% versus 39%). Monitor heart rate at regular intervals and instruct patients to report palpitations or feelings of a racing heartbeat while at rest. If patients experience a sustained increase in resting heart rate, discontinue Wegovy®
- **Suicidal Behavior and Ideation:** Suicidal behavior and ideation have been reported in clinical trials with other weight management products. Monitor patients for depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Discontinue Wegovy® in patients who

experience suicidal thoughts or behaviors and avoid in patients with a history of suicidal attempts or active suicidal ideation

- **Pulmonary Aspiration During General Anesthesia or Deep Sedation:** Wegovy® delays gastric emptying. There have been rare postmarketing reports of pulmonary aspiration in patients receiving GLP-1 receptor agonists undergoing elective surgeries or procedures requiring general anesthesia or deep sedation who had residual gastric contents despite reported adherence to preoperative fasting recommendations. Instruct patients to inform healthcare providers prior to any planned surgeries or procedures if they are taking Wegovy®

Adverse Reactions

- Most common adverse reactions (incidence ≥5%) are: nausea, diarrhea, vomiting, constipation, abdominal pain, headache, fatigue, dyspepsia, dizziness, abdominal distention, eructation, hypoglycemia in patients with type 2 diabetes, flatulence, gastroenteritis, gastroesophageal reflux disease, and nasopharyngitis

Drug Interactions

- The addition of Wegovy® in patients treated with insulin has not been evaluated. When initiating Wegovy®, consider reducing the dose of concomitantly administered insulin secretagogues (such as sulfonylureas) or insulin to reduce the risk of hypoglycemia
- Wegovy® causes a delay of gastric emptying and has the potential to impact the absorption of concomitantly administered oral medications. Monitor the effects of oral medications concomitantly administered with Wegovy®

Use in Specific Populations

- **Pregnancy:** May cause fetal harm. When pregnancy is recognized, discontinue Wegovy®. Discontinue Wegovy® in patients at least 2 months before planned pregnancy
- **Pediatric:** Adverse reactions with Wegovy® in pediatric patients aged 12 years and older with obesity were similar to those reported in adults in weight reduction trials. Pediatric patients ≥12 years of age treated with Wegovy® had greater incidences of cholelithiasis, cholecystitis, hypotension, rash, and urticaria compared to adults treated with Wegovy®. There are insufficient data in pediatric patients with type 2 diabetes treated with Wegovy® for obesity to determine if there is an increased risk of hypoglycemia with Wegovy® treatment similar to that reported in adults
- **Geriatric:** In the cardiovascular outcomes trial, patients aged 75 years and older reported more hip and pelvis fractures on Wegovy® than placebo. Patients aged 75 years and older (Wegovy® and placebo) reported more serious adverse reactions overall compared to younger adult patients

Please see Important Safety Information throughout. Please [click here](#) for Prescribing Information, including Boxed Warning.

Reference: 1. Wegovy® [package insert]. Plainsboro, NJ: Novo Nordisk Inc.



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