HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use WEGOVY safely and effectively. See full prescribing information for WEGOVY.

WEGOVY (semaglutide) injection, for subcutaneous use
Initial U.S. Approval: 2017

WARNING: RISK OF THYROID C-CELL TUMORS
See full prescribing information for complete boxed warning.

- **In rodents, semaglutide causes 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 the human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined (5.1, 13.1).**
- **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 of MTC and symptoms of thyroid tumors (4, 5.1).**

·····RECENT MAJOR CHANGES·····

Indications and Usage (1)	03/2024
Dosing and Administration (2.2)	07/2023
Warnings and Precaution, Hypoglycemia (5.4)	03/2024

·····INDICATIONS AND USAGE·····
WEGOVY is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated in combination with a reduced calorie diet and increased physical activity:

- to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight (1).
- to reduce excess body weight and maintain weight reduction long term in:
  - Adults and pediatric patients aged 12 years and older with obesity
  - Adults with overweight in the presence of at least one weight-related comorbid condition (1).

Limitations of Use:

- Coadministration with other semaglutide-containing products or with any other GLP-1 receptor agonist is not recommended (1).

·····DOSAGE AND ADMINISTRATION·····

- Administer WEGOVY once weekly as an adjunct to diet and increased physical activity, on the same day each week, at any time of day, with or without meals (2.1).
- Inject subcutaneously in the abdomen, thigh or upper arm (2.1).
- In patients with type 2 diabetes, monitor blood glucose prior to starting and during WEGOVY treatment (2.1).
- Initiate at 0.25 mg once weekly for 4 weeks. Then follow the dosage escalation schedule, titrating every 4 weeks to achieve the maintenance dosage (2.2, 2.3).
- The maintenance dosage of WEGOVY in adults is either 2.4 mg (recommended) or 1.7 mg once weekly (2.2).
- The maintenance dosage of WEGOVY in pediatric patients aged 12 years and older is 2.4 mg once weekly (2.3).

·····DOSAGE FORMS AND STRENGTHS·····
Injection: pre-filled, single-dose pen that delivers doses of 0.25 mg, 0.5 mg, 1 mg, 1.7 mg or 2.4 mg (3).

·····CONTRAINDICATIONS·····

- Personal or family history of MTC or in patients with MEN2 (4).
- Known hypersensitivity to semaglutide or any of the excipients in WEGOVY (4).

·····WARNINGS AND PRECAUTIONS·····

- *Acute Pancreatitis:* Has occurred in clinical trials. Discontinue promptly if pancreatitis is suspected. Do not restart if pancreatitis is confirmed (5.2).
- *Acute Gallbladder Disease:* Has occurred in clinical trials. If cholelithiasis is suspected, gallbladder studies and clinical follow-up are indicated (5.3).
- *Hypoglycemia:* Concomitant use with insulin or an insulin secretagogue may increase the risk of hypoglycemia, including severe hypoglycemia. Reducing the dose of insulin or insulin secretagogue may be necessary. Inform all patients of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia (5.4).
- *Acute Kidney Injury:* Has occurred. Monitor renal function when initiating or escalating doses of WEGOVY in patients reporting severe adverse gastrointestinal reactions or in those with renal impairment reporting severe adverse gastrointestinal reactions (5.5).
- *Hypersensitivity Reactions:* Anaphylactic reactions and angioedema have been reported postmarketing. Discontinue WEGOVY if suspected and promptly seek medical advice (5.6).
- *Diabetic Retinopathy Complications in Patients with Type 2 Diabetes:* Has been reported in trials with semaglutide. Patients with a history of diabetic retinopathy should be monitored (5.7).
- *Heart Rate Increase:* Monitor heart rate at regular intervals (5.8).
- *Suicidal Behavior and Ideation:* Monitor for depression or suicidal thoughts. Discontinue WEGOVY if symptoms develop (5.9).

·····ADVERSE REACTIONS·····
Most common adverse reactions (incidence ≥ 5%) in adults or pediatric patients aged 12 years and older are: nausea, diarrhea, vomiting, constipation, abdominal pain, headache, fatigue, dyspepsia, dizziness, abdominal distension, eructation, hypoglycemia in patients with type 2 diabetes, flatulence, gastroenteritis, gastroesophageal reflux disease, and nasopharyngitis (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Novo Nordisk Inc., at 1-833-934-6891 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------
WEGOVY delays gastric emptying. May impact absorption of concomitantly administered oral medications. Use with caution (7.2).

·····USE IN SPECIFIC POPULATIONS·····

- *Pregnancy:* May cause fetal harm. When pregnancy is recognized, discontinue WEGOVY (8.1).
- *Females and Males of Reproductive Potential:* Discontinue WEGOVY at least 2 months before a planned pregnancy because of the long half-life of semaglutide (8.3).

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 03/2024

FULL PRESCRIBING INFORMATION: CONTENTS*
WARNING: RISK OF THYROID C-CELL TUMORS

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING 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 *[see Warnings and Precautions (5.1) and Nonclinical Toxicology (13.1)]*.**
- **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) *[see Contraindications (4)]*. 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 *[see Contraindications (4) and Warnings and Precautions (5.1)]*.**

1 INDICATIONS AND USAGE

WEGOVY is indicated in combination with a reduced calorie diet and increased physical activity:

- to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight.

- to reduce excess body weight and maintain weight reduction long term in:
  - Adults and pediatric patients aged 12 years and older with obesity
  - Adults with overweight in the presence of at least one weight-related comorbid condition.

Limitations of Use

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

2 DOSAGE AND ADMINISTRATION

2.1 Important Monitoring and Administration Instructions

- In patients with type 2 diabetes, monitor blood glucose prior to starting WEGOVY and during WEGOVY treatment *[see Warnings and Precautions (5.4)]*.
- Prior to initiation of WEGOVY, train patients on proper injection technique. Refer to the accompanying Instructions for Use for complete administration instructions with illustrations.
- Inspect WEGOVY visually prior to each injection. Only use if solution is clear, colorless, and contains no particles.
- Administer WEGOVY in combination with a reduced-calorie diet and increased physical activity.
- Administer WEGOVY once weekly, on the same day each week, at any time of day, with or without meals.
- Inject WEGOVY subcutaneously in the abdomen, thigh, or upper arm. The time of day and the injection site can be changed without dose adjustment.

2.2 Recommended Dosage in Adults

Dosage Initiation and Escalation

- Initiate WEGOVY with a dosage of 0.25 mg injected subcutaneously once weekly. Then follow the dose escalation schedule presented in Table 1 to minimize gastrointestinal adverse reactions *[see Adverse*

- If patients do not tolerate a dose during dosage escalation, consider delaying dosage escalation for 4 weeks.

Table 1. Recommended Dosage Regimen for Adults

Treatment	Weeks	Once weekly Subcutaneous Dosage
Initiation	1 through 4	0.25 mg
Escalation	5 through 8	0.5 mg
	9 through 12	1 mg
	13 through 16	1.7 mg
Maintenance	17 and onward	1.7 mg or 2.4 mg

Maintenance Dosage

- The maintenance dosage of WEGOVY in adults is either 2.4 mg (recommended) or 1.7 mg once weekly. Consider treatment response and tolerability when selecting the maintenance dosage *[see Clinical Studies (14.2)]*.

2.3 Recommended Dosage in Pediatric Patients Aged 12 Years and Older

Dosage Initiation and Escalation

- Initiate WEGOVY according to the dosage escalation schedule in Table 2 to minimize gastrointestinal adverse reactions *[see Adverse Reactions (6.1)]*.
- If patients do not tolerate a dose during dosage escalation, consider delaying dosage escalation for 4 weeks.
- The 0.25 mg. 0.5 mg, and 1 mg once-weekly dosages are initiation and escalation dosages and are not approved as maintenance dosages.

Table 2. Recommended Dosage Regimen for Pediatric Patients Aged 12 Years and Older

Treatment	Weeks	Once weekly Subcutaneous Dosage
Initiation	1 through 4	0.25 mg[a]
Escalation	5 through 8	0.5 mg[a]
	9 through 12	1 mg[a]
	13 through 16	1.7 mg[b]
Maintenance	17 and onward	2.4 mg

[a]Not approved as maintenance dosages
[b]See *Dosage Modifications for Adverse Reactions*

Maintenance Dosage

- The maintenance dosage of WEGOVY in pediatric patients aged 12 years and older is 2.4 mg once weekly.

Dosage Modifications for Adverse Reactions

- If patients do not tolerate the 2.4 mg once-weekly maintenance dosage, the maintenance dosage may be reduced to 1.7 mg once weekly.
- Discontinue WEGOVY if the patient cannot tolerate the 1.7 mg once-weekly dosage.

2.4 Recommendations Regarding Missed Dose

- If one dose is missed and the next scheduled dose is more than 2 days away (48 hours), administer WEGOVY as soon as possible. If one 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 week.
- If 2 or more consecutive doses are missed, resume dosing as scheduled or, if needed, reinitiate WEGOVY and follow the dose escalation schedule, which may reduce the occurrence of gastrointestinal symptoms associated with reinitiation of treatment.

3 DOSAGE FORMS AND STRENGTHS

Injection: clear, colorless solution available in 5 pre-filled, disposable, single-dose pens:

- 0.25 mg/0.5 mL
- 0.5 mg/0.5 mL
- 1 mg/0.5 mL
- 1.7 mg/0.75 mL
- 2.4 mg/0.75 mL

4 CONTRAINDICATIONS

WEGOVY is contraindicated in the following conditions:

- A personal or family history of MTC or in patients with MEN 2 *[see Warnings and Precautions (5.1)]*.
- 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 *[see Warnings and Precautions (5.6)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Risk of Thyroid C-Cell Tumors

In mice and rats, semaglutide caused a dose-dependent and treatment-duration-dependent increase in the incidence of thyroid C-cell tumors (adenomas and carcinomas) after lifetime exposure at clinically relevant plasma exposures *[see Nonclinical Toxicology (13.1)]*. It is unknown whether WEGOVY causes thyroid C-cell tumors, including MTC, in humans, as human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined.

Cases of MTC in patients treated with liraglutide, another GLP-1 receptor agonist, have been reported in the postmarketing period; the data in these reports are insufficient to establish or exclude a causal relationship between MTC and GLP-1 receptor agonist use in humans.

WEGOVY is contraindicated in patients with a personal or family history of MTC or in patients with 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. Such monitoring may increase the risk of unnecessary procedures, due to the low test specificity for serum calcitonin and a high background incidence of thyroid disease. Significantly elevated serum calcitonin value may indicate MTC and patients with MTC usually have calcitonin values greater than 50 ng/L. If serum calcitonin is measured and found to be elevated, the patient should be further evaluated. Patients with thyroid nodules noted on physical examination or neck imaging should also be further evaluated.

5.2 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 semaglutide. Acute pancreatitis was observed in

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