Semaglutide/Cyanocobalamin (Vitamin B12)

This is a compounded medication, made in a licensed compounding pharmacy. Compounded drugs are not FDA-approved. Because of potential patent infringement these compounded medications must be made slightly different that the branded medication. This formulation of Semaglutide has vitamin B-12 mixed with it, so that it does not interfere with the branded medications patent.

Semaglutide is a glucagon-like peptide-1 receptor agonist; it mimics the action of the incretin GLP-1. GLP-1 is responsible for:

- increasing the production of insulin, a hormone that lowers the blood sugar level.
- enhancing growth of pancreatic beta cells, which are responsible for insulin production and release.
- Inhibiting the production of **glucagon**, which is a hormone that increases **glycogenolysis** (release of stored carbohydrate from the liver) and **gluconeogenesis** (synthesis of new glucose).
- Reducing food intake by lowering appetite and slowing down digestion in the stomach, helping to reduce body fat.
- Its half-life in the blood is about seven days (165–184 hours).

This medication has shown to be safe and effective to help lose large amounts of weight and keep it off.

Studys

Glucagon-Like Peptide 1 Receptor Agonists for Type 2 Diabetes

Once-Weekly Semaglutide in Adults with Overweight or Obesity

Important Safety Information for Semaglutide injection

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 Semaglutide 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.
- Semaglutide is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Semaglutide and inform them of symptoms of thyroid tumors (eg, 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 Semaglutide.

Indications and Limitations of Use

Semaglutide injection 0.5 mg, 1 mg, or 2 mg is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus and to reduce the risk of major adverse cardiovascular (CV) events (CV death, nonfatal myocardial infarction, or nonfatal stroke) in adults with type 2 diabetes mellitus and established CV disease.

- Semaglutide has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Semaglutide is not indicated for use in patients with type 1 diabetes mellitus.

Important Safety Information cont.

Contraindications

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

Warnings and Precautions

- **Risk of Thyroid C-Cell Tumors**: Patients should be referred to an endocrinologist for further evaluation if serum calcitonin is measured and found to be elevated or thyroid nodules are noted on physical examination or neck imaging.
- **Pancreatitis**: Acute and chronic pancreatitis have been reported in clinical studies. Observe patients carefully for signs and symptoms of pancreatitis (persistent severe abdominal pain, sometimes radiating to the back with or without vomiting). If pancreatitis is suspected, discontinue Semaglutide promptly, and if pancreatitis is confirmed, do not restart.
- **Diabetic Retinopathy Complications**: In a 2-year trial involving patients with type 2 diabetes and high cardiovascular risk, more events of diabetic retinopathy complications occurred in patients treated with Ozempic ® (3.0%) compared with placebo (1.8%). The absolute risk increase for diabetic retinopathy complications was larger among patients

with a history of diabetic retinopathy at baseline than among patients without a known history of diabetic retinopathy. Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. The effect of long-term glycemic control with semaglutide on diabetic retinopathy complications has not been studied. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy.

- Never Share a Semaglutide Pen Between Patients: Semaglutide pens must never be shared between patients, even if the needle is changed. Pen-sharing poses a risk for transmission of blood-borne pathogens.
- **Hypoglycemia**: Patients receiving Semaglutide in combination with an insulin secretagogue (eg, sulfonylurea) or insulin may have an increased risk of hypoglycemia, including severe hypoglycemia. Inform patients using these concomitant medications of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia.
- **Acute Kidney Injury**: There have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis, in patients treated with GLP-1 receptor agonists. Some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function when initiating or escalating doses of Semaglutide in patients reporting severe adverse gastrointestinal reactions.
- **Hypersensitivity**: Serious hypersensitivity reactions (eg, anaphylaxis, angioedema) have been reported in patients treated with Semaglutide. If hypersensitivity reactions occur, discontinue use of Semaglutide; treat promptly per standard of care, and monitor until signs and symptoms resolve. Use caution in a patient with a history of angioedema or anaphylaxis with another GLP-1 receptor agonist.
- **Acute Gallbladder Disease**: Acute events of gallbladder disease such as cholelithiasis or cholecystitis have been reported in GLP-1 receptor agonist trials and postmarketing. In placebo-controlled trials, cholelithiasis was reported in 1.5% and 0.4% of patients treated with Semaglutide 0.5 mg and 1 mg, respectively, and not reported in placebo-treated patients. If cholelithiasis is suspected, gallbladder studies and appropriate clinical follow-up are indicated.

Adverse Reactions

- The most common adverse reactions, reported in ≥5% of patients treated with Semaglutide are nausea, vomiting, diarrhea, abdominal pain, and constipation.

Drug Interactions

- When initiating Semaglutide, consider reducing the dose of concomitantly administered insulin secretagogue (such as sulfonylureas) or insulin to reduce the risk of hypoglycemia.
- Semaglutide causes a delay of gastric emptying and has the potential to impact the absorption of concomitantly administered oral medications, so caution should be exercised.

Use in Specific Populations

- There is limited data with semaglutide use in pregnant women to inform a drug-associated risk for adverse developmental outcomes. Discontinue Semaglutide in women at least 2 months before a planned pregnancy due to the long washout period for semaglutide.