

PRESCRIPTION MONOGRAPH

Compounded Active Ingredients: Semaglutide/Pyridoxine HCL

Form: Injection

Drug Class:

- Semaglutide: glucagon-like peptide-1 (GLP-1) receptor agonist.
 - Pyridoxine Hydrochloride: Vitamin B-6
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Mechanism of Action^{1,2,3}: Semaglutide is a synthetic analog of human GLP-1 that binds to and activates the GLP-1 receptor. When compounded with Pyridoxine Hydrochloride, it is intended to:

- Enhance insulin secretion in a glucose-dependent manner
 - Suppress glucagon secretion
 - Slow gastric emptying
 - Reduce food intake via central appetite regulation
 - Slow and prevent further liver damage caused by fat build-up and inflammation
 - Help reduce symptoms such as nausea and vomiting
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Indications Commonly Prescribed For:

- Type 2 Diabetes Mellitus (T2DM), adjunct to diet and exercise to improve glycemic control
 - Chronic Weight Management
 - Non-cirrhotic metabolic dysfunction-associated steatohepatitis (MASH)
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Before Use: Let your healthcare provider know if you have had any allergic reactions to injections in the past. Let your provider know if you are pregnant or breast feeding. Let your provider know of all supplements you are currently taking. Let your provider know about any health conditions you may have. Let your provider know if you are taking other medications containing benzyl alcohol.

Cautions⁴: Let your healthcare provider know of any changes of vision while on this compounded preparation. Take care when injecting the compounded preparation into only specified areas from your healthcare provider. Check the vial before use for any cloudiness or discoloration before use. Rotate your injection site with each injection to avoid skin problems like thinning, thickening, or lumps. Advise all your healthcare providers that you are taking a GLP-1 before you are scheduled to have surgery or other procedures. GLP-1s may cause serious side effects, including food or liquid getting into the lungs during surgery or other procedures that use anesthesia or deep sedation.

Contraindications⁴:

- Personal or family history of Medullary Thyroid Carcinoma (MTC)
 - Personal or family history of Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
 - Hypersensitivity to Semaglutide, Benzyl Alcohol, or its other components
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Warnings and Precautions⁴:

- Thyroid C-cell tumors: Inform your provider if you experience the following symptoms:
 - Mass in the neck
 - Dysphagia (difficulty swallowing)
 - Dyspnea (shortness of breath)
 - Persistent hoarseness
- Pancreatitis risk: inflammation of the pancreas, which can present with severe abdominal pain
- Hypoglycemia risk (especially with sulfonylureas or insulin)
- Acute kidney injury (due to volume depletion)
- Severe Gastrointestinal Events: Beyond nausea and constipation, warnings highlight severe, persistent vomiting and diarrhea, which can lead to dangerous dehydration
- Cardiovascular risk: Observe caution as increases in heart rate can worsen heart conditions
- Ileus (Intestinal Blockage): risk of ileus, a condition where the intestines fail to move normally, causing severe constipation, abdominal pain, and vomiting
- Gastroparesis: delayed gastric emptying can lead to gastroparesis (stomach paralysis)
- Pulmonary Aspiration Risk: reports of pulmonary aspiration (inhaling food into the lungs) in patients with delayed gastric emptying while undergoing anesthesia for procedures
- PR Interval Prolongation: Caution in patients with pre-existing conduction system abnormalities
- Benzyl alcohol is a preservative used in Pyridoxine Hydrochloride/Semaglutide. Metabolic acidosis can develop when large amounts of benzyl alcohol build up in your body.

Serious Warnings and Precautions⁴: Risk of Thyroid C-Cell Tumors:

- In rodents, Semaglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors (adenomas and carcinomas) at clinically relevant exposures. It is unknown whether this compound causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC) in humans as human relevance has not been established.
- Pyridoxine Hydrochloride/Semaglutide is contraindicated in patients with a personal or family history of MTC or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). It is unknown whether monitoring serum calcitonin or thyroid ultrasound will mitigate human risk of thyroid C-cell tumors. Patients should be counseled regarding the risk and symptoms of thyroid tumors.

Interactions⁴:

- May alter the absorption of oral medications due to delayed gastric emptying
- Caution with insulin or insulin secretagogues (increased hypoglycemia risk)
- Avoid combination with other semaglutide-containing drug or any other GLP-1 receptor agonist
- Monitoring recommended with warfarin/coumarin derivatives
- Use Caution during co-administration with drugs that prolong the PR interval or increase heart rate
- Use caution with other medications containing benzyl alcohol

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Adverse Reactions^{2,3,4}: If you experience any side effects or adverse reactions, including those not listed, please contact your healthcare provider. Seek emergency care if symptoms are severe.

Common:

- Nausea, vomiting, diarrhea
- Indigestion
- Delayed gastric emptying
- Constipation, bloating, gas
- Decreased appetite
- Mood and/or behavioral changes
- Dehydration
- Dyspepsia
- GERD
- Fatigue, Dizziness, Headache
- Hair loss
- Hypotension
- Taste Changes, Dry Mouth
- Hemorrhoids
- Dysesthesia
- Increase of pancreatic enzymes

Rare, but Serious:

- Acute Pancreatitis
- Diabetic Retinopathy
- Pulmonary aspiration during surgery
- Hypoglycemia
- Thyroid tumors
- Gastroparesis
- Malnutrition
- Anaphylactic reactions
- Suicidal Ideation and Behavior
- Acute Renal Failure
- Acute Kidney Injury
- Acute Gallbladder Disease
- Bone Fractures
- Appendicitis
- Angioedema
- Syncope

Use in Specific Populations⁴:

- Pregnancy: Contraindicated (Discontinue at least 2 months prior if planning to become pregnant)
- Lactation: Contraindicated (Unknown if excreted in breast milk).
- Pediatrics: Approved for use in adolescents ≥ 12 years with obesity
- Hepatic Impairment: No dose adjustment needed. Use with caution and monitor.
- Renal Impairment: Not recommended with end stage renal impairment.

Storage:

- Refrigerate at 2°C to 8°C (36°F to 46°F)
- Can be stored at room temperature (up to 30°C or 86°F) for up to 48hrs
- Do not freeze

How to Use: This medication is a subcutaneous injection and is delivered in a premixed liquid form. Wash your hands with soap and water before giving the injection. Wipe the rubber stopper of the vial with an alcohol swab. Take a syringe and pull the plunger down to the necessary prescribed amount. This is achieved when the plunger reaches the line for the amount prescribed. Push the needle through the rubber stopper of the vial. Push the plunger down to put air into the vial. Invert the vial and then slowly pull the plunger down past the prescribed dose. If there are bubbles in the syringe, tap the syringe to allow the air bubbles to rise to the top. Slowly push the plunger up until the tip reaches the line for the prescribed dose and removes the bubble of air. Pull the syringe out of the vials rubber stopper. Inject at predetermined injection site as instructed by healthcare practitioner. Discard any remainder from punctured vial after 28 days.

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Monitoring Parameters:

- Blood glucose and HbA1c
 - Renal function (especially during gastrointestinal adverse events)
 - Signs of pancreatitis or thyroid tumors – refer patient to an endocrinologist for further evaluation if the following are detected:
 - Elevated serum calcitonin
 - Thyroid nodules
 - Weight and appetite changes
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Citations:

1. Tasyurek HM, Altunbas HA, Balci MK, Sanlioglu S. Incretins: Their physiology and application in the treatment of diabetes mellitus. *Diabetes Metab Res Rev*. 2014;30:354–371. doi: 10.1002/dmrr.2501.
2. Sahakian V, Rouse D, Sipes S, Rose N, Niebyl J. Vitamin B6 is effective therapy for nausea and vomiting of pregnancy: a randomized, double-blind placebo-controlled study. *Obstet Gynecol*. 1991 Jul;78(1):33-6. PMID: 2047064.
3. Bendicho-Lavilla C, Seoane-Viaño I, Otero-Espinar FJ, Luzardo-Álvarez A. Fighting type 2 diabetes: Formulation strategies for peptide-based therapeutics. *Acta Pharm Sin B*. 2022;12(2):621-636. doi:10.1016/j.apsb.2021.08.003
4. Safety information referenced from the FDA-approved labeling for Semaglutide: Novo Nordisk Canada Inc. *Wegovy (semaglutide) Product Monograph*. Mississauga, ON: Novo Nordisk Canada Inc.; 2023. Available from: <https://www.novonordisk.ca/content/dam/nncorp/ca/en/products/Wegovy-product-monograph.pdf>. Accessed February 2, 2026.