

# PRESCRIPTION MONOGRAPH

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**Compounded Active Ingredients:** Semaglutide/Pyridoxine HCL

**Form:** Sublingual Rapid Dissolve Tablet

**Drug Class:**

- Semaglutide: Glucagon-like peptide-1 (GLP-1) receptor agonist
- Pyridoxine: Vitamin B-6

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**Mechanism of Action**<sup>1,2,3</sup>: 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 any medication allergies before you take this compounded preparation. Let your provider know if you are pregnant or breast feeding. Let your provider know if you have any liver or kidney problems. Let your provider know of all supplements you are currently taking. Let your provider know about any health conditions you may have.

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**Contraindications**<sup>4</sup>:

- 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 or its components

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**Cautions**<sup>4</sup>: Let your healthcare provider know of any changes of vision while on this compounded preparation. 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.

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## Warnings and Precautions<sup>4</sup>:

- 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)
- PR Interval Prolongation: Caution in patients with pre-existing conduction system abnormalities
- Pulmonary Aspiration Risk: reports of pulmonary aspiration (inhaling food into the lungs) in patients with delayed gastric emptying while undergoing anesthesia for procedures

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## Serious Warnings and Precautions<sup>4</sup>: 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 Pyridoxine Hydrochloride/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.
- 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.

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## Interactions<sup>4</sup>:

- 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

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**Adverse Reactions**<sup>2,3,4</sup>: 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

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### Use in Specific Populations<sup>4</sup>:

- Pregnancy: Contraindicated (Discontinue at least 2 months prior if planning to become pregnant).
- Lactation: Contraindicated (Unknown if excreted in breast milk).
- Pediatrics: Safety and effectiveness have not been established.
- Hepatic Impairment: No dose adjustment needed. Use with caution and monitor.
- Renal Impairment: Not recommended with end stage renal impairment.

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### Storage:

- Store in original container at room temperature (up to 30°C or 86°F)
- Store in a cool dry place away from heat, sunlight, and moisture

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**How to Use:** This compounded preparation is in the form of a sublingual rapid dissolve tablet. Place tablet under tongue to dissolve completely. Do not chew or crush the tablet. Once the tablet has fully dissolved, do not rinse your mouth, brush your teeth, or consume food or beverages for at least five minutes to allow absorption. If you miss a dose, take as soon as you remember, but not at the time for the next dose. The desired results may take up to several weeks.

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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: U.S. Food and Drug Administration. *Rybelsus (semaglutide) tablets, for oral use: Prescribing information*. Silver Spring, MD: FDA; 2024. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2024/213051s018lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/213051s018lbl.pdf). Accessed February 2, 2026.