

# **PRESCRIPTION MONOGRAPH**

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

**Form:** Nasal Spray

## **Drug Class:**

- Semaglutide is a glucagon-like peptide-1 (GLP-1) receptor agonist. It attaches to the GLP-1 receptor in the body to illicit its effects. GLP-1 receptors when activated can initiate insulin secretion, cause delayed gastric emptying, and reduce appetite<sup>1</sup>.
  - Pyridoxine (Vitamin B-6) is B vitamin has also been found to be useful in preventing nausea and vomiting<sup>2</sup>.
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## **Mechanism of Action<sup>3</sup>:**

Semaglutide is a synthetic analog of human GLP-1 that binds to and activates the GLP-1 receptor. It is intended to:

- Enhance glucose-dependent insulin secretion
  - Suppress inappropriate post-meal glucagon release
  - Delay gastric emptying
  - Reduce food intake via central appetite regulation
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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
  - Cardiovascular Risk Reduction
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**Before Use:** Let your doctor know if you have had any allergic reactions to nasal sprays in the past. Let your health care provider know if you are pregnant or breast feeding. Let your healthcare provider know of all supplements you are currently taking.

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## **Contraindications:**

- Personal or family history of medullary thyroid carcinoma
  - Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
  - Hypersensitivity to semaglutide or its components
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**Cautions:** Let your Healthcare provider know of any changes of vision while on this compounded preparation. Advise all your health care 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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**How to Use:** This medication is a nasal spray and is delivered in a premixed liquid form. Gently blow your nose to clear it from mucous before using the compound. Remove the ring and protective cap to reveal the nasal spray tip. Tilt head slightly forward, hold bottle with thumb on bottom and your index and middle fingers on top. Use your fingers to squeeze down on the pump while you breathe in slowly through your nose. If needed, repeat the process for the second nostril.

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## Warnings and Precautions:

- Thyroid C-cell tumors (boxed warning)
  - Pancreatitis risk
  - Diabetic retinopathy complications
  - Hypoglycemia risk (especially with sulfonylureas or insulin)
  - Acute kidney injury (due to volume depletion)
  - Acute gallbladder disease
  - Gastrointestinal adverse events (nausea, vomiting, diarrhea)
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## Adverse Reactions:

### Common:

- Nausea
- Vomiting
- Diarrhea
- Constipation
- Abdominal pain
- Decreased appetite

### Serious:

- Pancreatitis
  - Gallbladder disease (cholelithiasis/cholecystitis)
  - Diabetic retinopathy complications
  - Hypersensitivity reactions (e.g., anaphylaxis)
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## Interactions:

- May alter the absorption of oral medications due to delayed gastric emptying
  - Caution with insulin or insulin secretagogues (increased hypoglycemia risk)
  - Consider timing when co-administering oral medications with narrow therapeutic index
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## Use in Specific Populations:

- Pregnancy: Limited human data; discontinue at least 2 months prior to a planned pregnancy
  - Lactation: Unknown if excreted in human milk; use with caution
  - Pediatrics: Approved for use in adolescents  $\geq 12$  years with obesity
  - Renal Impairment: No dose adjustment recommended, but monitor renal function
  - Hepatic Impairment: Use with caution; no dose adjustment generally needed
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## 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
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## Monitoring Parameters:

- Blood glucose, HbA1c
- Renal function, especially during GI side effects
- Weight
- Signs of pancreatitis
- Progression of diabetic retinopathy
- Adverse GI symptoms

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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
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Compounded medications are not FDA-approved and may differ in risks, benefits, and side effects from FDA-approved products. These statements have not been evaluated by the FDA and are not intended to diagnose, treat or cure any disease or condition and do not indicate any claims of safety or efficacy.

Individual results may vary.