

PRESCRIPTION MONOGRAPH

Compounded Active Ingredients: Semaglutide/Pyridoxine HCL

Form: Injection

Drug Class:

- Semaglutide is a glucagon-like peptide-1 (GLP-1) receptor agonist¹.
 - Pyridoxine (Vitamin B-6) is B vitamin intended to prevent nausea and vomiting².
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Mechanism of Action³:

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

These effects can contribute to improved glycemic control and significant weight loss.

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 injections 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.

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: Take care when injecting the compounded preparations into only specified areas from your health care provider. Check the vial before use for any cloudiness or discoloration before use. 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.

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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Warnings and Precautions:

- Thyroid C-cell tumors
 - 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 ≥ 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

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.