

# PRESCRIPTION MONOGRAPH

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

**Form:** Injection

**Drug Class:**

- Tirzepatide: dual GIP and GLP-1 receptor agonist<sup>1</sup>
  - Pyridoxine Hydrochloride: Vitamin B-6
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**Mechanism of Action**<sup>1,2,3</sup>: Tirzepatide is a synthetic polypeptide that activates both GIP and GLP-1 receptors. When compounded with Pyridoxine Hydrochloride, it is intended to:

- Enhance insulin secretion in a glucose-dependent manner
  - Suppress glucagon secretion
  - Slow gastric emptying
  - Promote satiety and reduce appetite, leading to weight loss
  - 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
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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.

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**Cautions**<sup>4</sup>: 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.

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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 Tirzepatide, Benzyl Alcohol, or its other components
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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)
- Pulmonary Aspiration Risk: reports of pulmonary aspiration (inhaling food into the lungs) in patients with delayed gastric emptying while undergoing anesthesia for procedures
- Malnutrition: events related to malnutrition have been reported including, but not limited to:
  - Vitamin and mineral deficiency
  - Protein deficiency
  - Low body weight
- Benzyl alcohol is a preservative used in Pyridoxine Hydrochloride/Tirzepatide. Metabolic acidosis can develop when large amounts of benzyl alcohol build up in your body.

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## Serious Warnings and Precautions<sup>4</sup>: Risk of Thyroid C-Cell Tumors:

- In rodents, Tirzepatide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors (adenomas and carcinomas) at clinically relevant exposures. It is unknown whether Pyridoxine Hydrochloride/Tirzepatide causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC) in humans as human relevance of Tirzepatide-induced rodent thyroid C-cell tumors has not been determined.
- Pyridoxine Hydrochloride/Tirzepatide 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 due to increased hypoglycemia risk
- Avoid combination with other GLP-1 Ras or DPP-4 inhibitors.
- May reduce effectiveness of oral contraceptives – advised to switch to a non-oral method.
- Caution with medications that increase heart rate such as drugs with sympathomimetic or anticholinergic activity.

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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
- Abdominal pain
- Decreased appetite
- Mood and/or behavioral changes
- Dehydration
- Dyspepsia
- GERD
- Fatigue, Dizziness
- Hair loss
- Hypotension
- Taste Changes, Dry Mouth
- Dysesthesia

### Rare, but Serious:

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

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

- Pregnancy: Contraindicated (Discontinue at least 1 month prior if planning to become pregnant)
- Lactation: Contraindicated (Unknown if excreted in breast milk).
- Pediatrics: Safety not established. Not recommended for patients under the age of 18.
- 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:

- 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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**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. Discard any remainder from punctured vial after 28 days from first use.

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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
  - Vitamin, Mineral, Protein levels – nutritional guidance, supplementation, and support should be considered in cases of malnutrition
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### Citations:

1. Willard FS, Douros JD, Gabe MB, Showalter AD, Wainscott DB, Suter TM, Capozzi ME, van der Velden WJ, Stutsman C, Cardona GR, Urva S, Emmerson PJ, Holst JJ, D'Alessio DA, Coghlan MP, Rosenkilde MM, Campbell JE, Sloop KW. Tirzepatide is an imbalanced and biased dual GIP and GLP-1 receptor agonist. *JCI Insight*. 2020 Sep 3;5(17):e140532. doi: 10.1172/jci.insight.140532. PMID: 32730231; PMCID: PMC7526454.
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. Rubino DM, Nauck MA, Wadden TA, et al. Continued treatment with tirzepatide for maintenance of weight reduction in adults with obesity: The SURMOUNT-4 randomized clinical trial. *JAMA*. 2025;333(14):1351-1363. doi:10.1001/jama.2025.11842. Available from: <https://jamanetwork.com/journals/jama/fullarticle/2812936>
4. Safety information referenced from the FDA-approved labeling for Tirzepatide: Eli Lilly Canada Inc. *Zepbound (tirzepatide) Product Monograph*. Toronto, ON: Eli Lilly Canada Inc; 2023. Available from: <https://pi.lilly.com/ca/zepbound-ca-pm.pdf>. Accessed February 2, 2026.