

SEMAGLUTIDE/PYRIDOXINE 1000MCG-25MG/ML Injection MDV (1ML & 4ML)

What is Semaglutide and Pyridoxine combination injection and how does it work?

Semaglutide: primarily belongs to the class of antidiabetic agents, more specifically Glucagon-Like Peptide-1.

Mechanisms of action:

- I. It works by stimulating glucose-dependent insulin release from the pancreatic islets.
- II. It has also been shown to slow gastric emptying
- III. Inhibits inappropriate post-meal glucagon release
- IV. Reduces food intake

It is an FDA approved product for patients with Type 2 Diabetes and chronic Obesity leading towards metabolic disease.

Pyridoxine: also known as Vitamin B6 is a critically needed nutrient for

- I. Providing a jumpstart in the metabolism of protein, carbohydrates, and fats
- II. Production of neurotransmitters and the formation of nicotinic acid
- III. Maintaining a health nervous system, skin, muscles, and blood
- IV. Stimulating effect on thyroid function and prevents water retention

When added to Semaglutide as an adjuvant ingredient, it could help to encourage weight loss by facilitating all health aspects of metabolism

What are the clinical uses of Semaglutide/Pyridoxine combination injection?

1. Diabetes mellitus, type 2, treatment: As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. This can cause risk reduction of major cardiovascular events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.
2. Weight management, chronic: As an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial BMI of 30kg/m² (obesity), or 27kg/m² (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia)

How Semaglutide/Pyridoxine combination injection should be used?

This injection should only be used as prescribed by the healthcare practitioner after complete evaluation. Once prescribed a titration protocol must be follow to determine a safe and effective dose for individually identified patient.

Prior to prescribing, monitoring parameters should include BMI, Hemoglobin A1c, thyroid, and other endocrine function tests to rule out cancer.

Weight management dosing protocol: For use as an adjunct to diet and exercise in patients with a BMI of 30kg/m², or in patients with a BMI of 27 kg/m² and one weight associated comorbidity (e.g. hypertension, dyslipidemia)

Initial dosage: Dosed as Semaglutide-Pyridoxine combination dose:

Dosage titration:

Adjust dosage using the following schedule: in patients who do not tolerate a dosage increase, consider delaying the increase for an additional 4 weeks

- I. Week 1 through 4: 0.25mg-6.25mg (0.25mL) subcutaneously every week; It will be dispensed in 1 mL for one month's supply
- II. Week 5 through 8: 0.5mg-12.5mg (0.5mL) subcutaneously every week; It will be dispensed in 1mL x 2 MDVs for one month's supply
- III. Week 9 and onward: 1mg-25mg (1.0mL) subcutaneously every week; It will be dispensed in 1x 4mL MDV 2 for one month's supply

Typically, this protocol is used for 3 months and if no results are seen discontinuation of the therapy is recommended. Texas Star Pharmacy does not recommend increasing the dose above 1mg of Semaglutide for moderate weight loss goals. However, it is up to the healthcare provider to determine the maximum dose per administration and duration of therapy.

Based on the available literature, maximum dose can be titrated from 1mg once weekly injection (week 9-12), to 1.7mg (week 13-16), and 2.4mg (week 17 and onward). Always be extra vigilant when higher doses are prescribed because as the dose increases so does the adverse effects and side effect profile.

What are the contraindications of Semaglutide/Pyridoxine injection therapy?

- I. Hypersensitivity to any Glucagon-Like Peptide
- II. Thyroid Cancer/Tumor
- III. Any type of endocrine (single or multiple) melanoma

What are the warnings/precautions to Semaglutide and Pyridoxine injection?

Here is a list of conditions where this product should be used with caution.

- I. Pancreatitis (dose related)
- II. Diabetic Retinopathy (in diabetic patients)
- III. Acute or chronic kidney injury/failure (in diabetic patients and dose related)
- IV. Gall bladder disease (for example Cholelithiasis when rapid/substantial weight loss is achieved)

- V. Delayed gastric emptying (affects the absorption and kinetics of other narrow therapeutic drugs used as concomitant therapy for other medical conditions)

What are the possible side effects of Semaglutide/Pyridoxine injection?

Gastrointestinal side effects comprise the majority of the side effect profile.

Diarrhea up to 10%, vomiting up to 9%, constipation up to 6%, abdominal distention and flatulence up to 3%, Gastroesophageal reflux disease up to 2% and Cholelithiasis less than 2%.

What if I miss my weekly dose that is supposed to be administered on a specific day of the week?

Take the missed dose as soon as you recall, but skip it completely if it's less than 48 hours before the next weekly dose.

How does Semaglutide/Pyridoxine injection come and how should it be stored?

Semaglutide/Pyridoxine comes in only one concentration as 1000mcg (1mg)/25mg per mL, multidose vial in 1mL and 4mL vials. The potency of the compounded preparation is assessed and validated for longer duration, but each vial shall be used up to 28-day period from the time of first puncture.

Opened and unopened vials must be stored in the refrigerator to maintain efficacy. Do not freeze the unopened vials.

References:

Facts and comparison Semaglutide and Pyridoxine injections

Pyridoxine - ResearchGate and PubChem & PubMed - NCBI

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