

VIOGEN

Pharmaceuticals.



Semaglutide 5mg.

INDICATIONS AND USAGE

- Semaglutide is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes mellitus.

DOSAGE AND ADMINISTRATION

- Box contains: 1x Semaglutide 5mg each (unconstituted) and 1x Bacteriostatic for injection 2mL.
- How to reconstitute: Remove both caps to the vials, using a 2mL or larger syringe with a 22 gauge needle, insert the needle into the Bacteriostatic water vial, remove the water from the vial into the syringe and place the water into the Tirzepatide vial. Allow to mix naturally, once reconstituted store below 4°C.
DO NOT SHAKE.
- The recommended starting dosage is 0.25mg/0.1mL injected subcutaneously once weekly.
- After 4 weeks, increase to 0.5mg/0.2mL injected subcutaneously once weekly.
- If additional glycemic control is needed, increase the dosage in 0.25mg/0.1mL increments after at least 4 weeks
- The maximum recommended dosage is 1mg subcutaneously once weekly.
- Administer once weekly at any time of day, with or without meals.
- Inject subcutaneously in the abdomen, thigh, or upper arm.
- Recommended to rotate injection sites with each administration.

CONTRAINDICATIONS

- Personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2
- Known serious hypersensitivity to tirzepatide or any of the excipients in SEMAGLUTIDE.

WARNINGS AND PRECAUTIONS

- Pancreatitis: Has been reported in clinical trials. Discontinue promptly if pancreatitis is suspected.
 - Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin: Concomitant use with an insulin secretagogue or insulin may increase the risk of hypoglycemia, including severe hypoglycemia. Reducing dose of insulin secretagogue or insulin may be necessary.
 - Hypersensitivity Reactions: Hypersensitivity reactions have been reported. Discontinue SEMAGLUTIDE if suspected.
 - Acute Kidney Injury: Monitor renal function in patients with renal impairment reporting severe adverse gastrointestinal reactions.
 - Severe Gastrointestinal Disease: Use may be associated with gastrointestinal adverse reactions, sometimes severe.
- Has not been studied in patients with severe gastrointestinal disease and is not recommended in these patients.
- Diabetic Retinopathy Complications in Patients with a History of Diabetic Retinopathy: Has not been studied in patients with non-proliferative diabetic retinopathy requiring acute therapy, proliferative diabetic retinopathy, or diabetic macular edema. Monitor patients with a history of diabetic retinopathy for progression.
 - Acute Gallbladder Disease: Has occurred in clinical trials. If cholelithiasis is suspected, gallbladder studies and clinical follow-up are indicated.)

ADVERSE REACTIONS

The most common adverse reactions, reported in $\geq 5\%$ of patients treated with SEMAGLUTIDE are: nausea, diarrhea decreased appetite, vomiting, constipation, dyspepsia, and abdominal pain.

DRUG INTERACTIONS

SEMAGLUTIDE delays gastric emptying and has the potential to impact the absorption of concomitantly administered oral medications.