VIOGEN
Pharmaceuticals.

Tirzepatide 10mg.

INDICATIONS AND USAGE

TIRZEPATIDE™ is a glucose-dependent insulinotropic polypeptide (GIP) receptor and 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 Tirzepatide 10mg (unconstituted) and 1x Bacteriostatic Water for Injection 2mL.
- How to reconsitute: Remove both caps to the vials, using a 2mL or larger syringe with a 22 guage 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 reconsituted store below 4°c.
  DO NOT SHAKE.
- The recommended starting dosage is 2.5mg/0.5mL injected subcutaneously once weekly.
- After 4 weeks, increase to 5mg/1mL injected subcutaneously once weekly.
- If additional glycemic control is needed, increase the dosage in 2.5mg/0.5mL increments after at least 4 weeks on the current dose.
- The maximum dosage is 15mg 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 TIRZEPATIDE

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 TIRZEPATIDE 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 ≥5% of patients treated with TIRZEPATIDE are: nausea, diarrhea decreased appetite, vomiting, constipation, dyspepsia, and abdominal pain.

DRUG INTERACTIONS

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