# Montaro™

Tirzepatide INN

**Composition**

**Montaro**™ 2.5 mg Injection: Each pre-filled syringe contains Tirzepatide INN 2.5 mg in 0.5 mL solution for Injection.

**Montaro**™ 5 mg Injection: Each pre-filled syringe contains Tirzepatide INN 5 mg in 0.5 mL solution for Injection.

**Pharmacology**

**Montaro**™ is a once weekly antihyperglycemic medication. **Montaro**™ contains an active substance called Tirzepatide which is used to treat adults with type 2 diabetes mellitus. Tirzepatide acts as a GLP-1/GIP receptor dual agonist that selectively binds to activates both the GLP-1 and GIP receptor, increases the activity of GLP-1 and GIP. **Montaro**™ reduces the blood sugar in the body through a mechanism of where it stimulates insulin secretion as well as lowers glucagon levels, both in glucose-dependent manner. Thus, when blood glucose is high, insulin secretion is stimulated and glucagon secretion is inhibited. The mechanism of blood glucose lowering also involves the delay in gastric emptying in the early postprandial phase. **Montaro**™ is used on its own when a patient can't take metformin or with other medicines for diabetes when they are not enough to control your blood sugar levels. These other medicines may be taken by mouth and/or insulin given by Injection. It is important to continue to follow the advice on diet and exercise given to patients by the physician.

**Indication**

**Montaro**™ 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 o improve glycemic control in adults with type-2 diabetes mellitus. It is also indicated for overweight or obesity with or without diabetes.

**Limitations of Use**

- Has not been studied in patients with a history of pancreatitis
- Is not indicated for use in patients with type 1 diabetes mellitus & Diabetes ketoacidosis

**Dosage and Administration**

**Montaro**™ is injected subcutaneously and can be taken at any time of the day, regardless of the timing of meals.

| Starting dose | Maintenance dose | For additional glycemic control |
|---|---|---|
| Start **Montaro**™ with 2.5 mg once weekly for 4 weeks. | After 4 weeks increase the dose to 5 mg once weekly. | If additional glycemic control is needed, increase the dosage in 2.5 mg increments after at least 4 weeks on the current dose. |

**Dose adjustment**

When Tirzepatide is added with metformin and/or thiazolidinedione therapy, the current dose of metformin and/or thiazolidinedione can be continued unchanged. When Tirzepatide is added with existing therapy of insulin secretogauge (sulfonylureas) or insulin, a reduction in the dose of sulfonylurea or insulin should be considered to reduce the risk of hypoglycemia. Blood glucose self-monitoring is necessary to adjust the dose of Tirzepatide is started and insulin is reduced.

**Missed Dose**

If a dose is missed, administer **Montaro**™ as soon as possible within 4 days (96 hours) after the missed dose.

**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 Precaution**

- 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 nonproliferative 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**

**Montaro**™ delays gastric emptying and has the potential to impact the absorption of concomitantly administered oral medications

**Use in specific populations**

- Pregnancy: based on animal study, may cause fetal harm.
- Females of reproductive potential: advise females using oral contraceptives to switch to a non-oral contraceptive method, or add a barrier method of contraception for 4 weeks after initiation and for 4 weeks after each dose escalation.

**Storage and Handling**

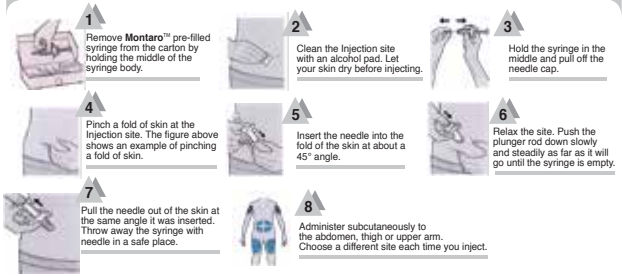
- Store at $2^0$ C to $8^0$ C ($36^0$ F to $46^0$ F) temperature in a refrigerator.
- If needed, each single-dose pre-filled syringe can be stored unrefrigerated at temperature not to exceed 30° C (86° F) for up to 21 days.
- Do not freeze. Do not use if frozen.
- Store **Montaro**™ in the original carton to protect from light.

**How supplied**

**Montaro**™ 2.5 mg Injection: Each box contains 1 pre-filled syringe of 0.5 mL solution of Tirzepatide INN 2.5 mg Injection in Alu-PVC blister pack.

**Montaro**™ 5 mg Injection: Each box contains 1 pre-filled syringe of 0.5 mL solution of Tirzepatide INN 5 mg Injection in Alu-PVC blister pack.

**Instructions for patient administration**




*Manufactured by*

SQUARE PHARMACEUTICALS PLC.

Bangladesh