Tirzix

Pre-filled syringe

Tirzepatide INN

COMPOSITION

TIRZIX 2.5 Injection: Each pre-filled syringe contains Tirzepatide INN 2.5 mg/0.5 mL.

TIRZIX 5 Injection: Each pre-filled syringe contains Tirzepatide INN 5 mg/0.5 mL.

TIRZIX 7.5 Injection: Each pre-filled syringe contains Tirzepatide INN 7.5 mg/0.5 mL.

TIRZIX 10 Injection: Each pre-filled syringe contains Tirzepatide INN 10 mg/0.5 mL.

TIRZIX 12.5 Injection: Each pre-filled syringe contains Tirzepatide INN 12.5 mg/0.5 mL.

TIRZIX 15 Injection: Each pre-filled syringe contains Tirzepatide INN 15 mg/0.5 mL.

INDICATIONS

Tirzepatide is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist indicated

Treatment for Obesity and Overweight:

As an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:

- 30 kg/m^2 or greater (obesity) or
- 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes mellitus, obstructive sleep apnea or cardiovascular disease)

Treatment for Type-2 Diabetes Mellitus:

As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

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.

DOSAGE AND ADMINISTRATION

The recommended starting dosage of Tirzepatide is 2.5 mg injected subcutaneously once weekly. After 4 weeks, increase to 5 mg injected subcutaneously 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. The maximum dosage is 15 mg subcutaneously once weekly. Administer once weekly at any time of day, with or without meals. Inject subcutaneously in the abdomen, thigh, or upper arm. Rotate injection sites with each dose.

Missed Dose: If a dose is missed, instruct patients to administer Tirzepatide as soon as possible within 4 days (96 hours) after the missed dose. If more than 4 days have passed, skip the missed dose and administer the next dose on the regularly scheduled day. In each case, patients can then resume their regular once-weekly dosing schedule.

Dose Adjustment: When initiating Tirzepatide, consider reducing the dose of concomitantly administered insulin secretagogues (e.g., sulfonylureas) or insulin to reduce the risk of hypoglycemia. When Tirzepatide is added to existing metformin therapy, the current dose of metformin can be continued unchanged.

CLINICAL PHARMACOLOGY

Pharmacodynamics

Tirzepatide lowers fasting and postprandial glucose concentration, decreases food intake, and reduces body weight in patients with type 2 diabetes mellitus. Tirzepatide enhances the first- and second-phase insulin secretion.

Pharmacokinetics

The pharmacokinetics of Tirzepatide is similar between healthy subjects and patients with type 2 diabetes mellitus. Steady-state plasma Tirzepatide concentrations were achieved following 4 weeks of once-weekly administration. Tirzepatide exposure increases in a dose-proportional manner.

Absorption

Following subcutaneous administration, the time to maximum plasma concentration of Tirzepatide ranges from 8 to 72 hours. The mean absolute bioavailability of Tirzepatide following subcutaneous administration is 80%. Similar exposure was achieved with subcutaneous administration of Tirzepatide in the abdomen, thigh, or upper arm.

Distribution

The mean apparent steady-state volume of distribution of Tirzepatide following subcutaneous administration in patients with type 2 diabetes mellitus is approximately 10.3 L. Tirzepatide is highly bound to plasma albumin (99%).

Elimination

The apparent population means clearance of Tirzepatide is 0.061 L/H with an elimination half-life of approximately 5 days, enabling once-weekly dosing.

Metabolism

Tirzepatide is metabolized by proteolytic cleavage of the peptide backbone, beta-oxidation of the C20 fatty diacid moiety, and amide hydrolysis.

Excretion

The primary excretion routes of Tirzepatide metabolites are via urine and feces. Intact Tirzepatide is not observed in urine or feces.

Mechanism of Action

Tirzepatide is a GIP receptor and GLP-1 receptor agonist. It is a 39-amino-acid modified peptide with a C20 fatty diacid moiety that enables albumin binding and prolongs the half-life. Tirzepatide selectively binds to and activates both the GIP and GLP-1 receptors, the targets for native GIP and GLP-1. Tirzepatide enhances first- and second-phase insulin secretion, and reduces glucagon levels, both in a glucose-dependent manner.

Contraindications:

Tirzepatide is contraindicated in patients with a 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 Injection.

Warning & 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 the 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.

Drug Interaction:

Tirzepatide delays gastric emptying, and thereby has the potential to impact the absorption of concomitantly administered oral medications. Hormonal contraceptives that are not administered orally should not be affected.

Adverse Reaction:

The most common adverse reactions, reported in ≥5% of patients treated with Tirzepatide are:

- Nausea.
- Diarrhea.
- Decreased Appetite.
- Vomiting.
- Constipation.
- Dyspepsia.
- Abdominal pain.

Use in Special Population:

Pregnancy & Lactation: There are risks to the mother and fetus associated with poorly controlled diabetes in pregnancy. Tirzepatide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Tirzepatide and any potential adverse effects on the breastfed infant from Tirzepatide or from the underlying maternal condition.

Pediatric Patients: Safety and effectiveness of Tirzepatide have not been established in pediatric patients (younger than 18 years of age).

Geriatric Patients: No overall differences in safety or efficacy were detected between older patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Renal Impairment: No dosage adjustment of Tirzepatide is recommended for patients with renal impairment. In subjects with renal impairment including end-stage renal disease (ESRD), no change in Tirzepatide pharmacokinetics (PK) was observed.

Hepatic Impairment: No dosage adjustment of Tirzepatide is recommended for patients with hepatic impairment. In a clinical pharmacology study in subjects with varying degrees of hepatic impairment, no change in Tirzepatide PK was observed.

PHARMACEUTICAL INFORMATION:

Storage Conditions

Keep out of the reach and sight of children. Store in a refrigerator at 2°C to 8°C. Do not freeze and protect from light. Do not use it if it has been frozen. To be taken and sold only on the prescription of a registered physician.

Presentation & Packaging

Tirzix 2.5 Injection: Each box contains 1 pre-filled syringe containing Tirzepatide INN 2.5 mg/0.5 mL and an alcohol pad.

Tirzix 5 Injection: Each box contains 1 pre-filled syringe containing Tirzepatide INN 5 mg/0.5 mL and an alcohol pad.

Tirzix 7.5 Injection: Each box contains 1 pre-filled syringe containing Tirzepatide INN 7.5 mg/0.5 mL and an alcohol pad.

Tirzix 10 Injection: Each box contains 1 pre-filled syringe containing Tirzepatide INN 10 mg/0.5 mL and an alcohol pad.

Tirzix 12.5 Injection: Each box contains 1 pre-filled syringe containing Tirzepatide INN 12.5 mg/0.5 mL and an alcohol pad.

Tirzix 15 Injection: Each box contains 1 pre-filled syringe containing Tirzepatide INN 15 mg/0.5 mL and an alcohol pad.

Only for Export

1300002896

Manufactured By
Beacon Pharmaceuticals PLC
Bhaluka, Mymensingh, Bangladesh

Marketed By
BEACON®
Medicare Limited
Dhaka, Bangladesh