Tirzema™

Tirzepatide Injection

Presentation

Tirzema™ 2.5 mg injection: Each pre-filled syringe contains Tirzepatide INN 2.5 mg in 0.5 ml solution for Injection.
Tirzema™ 5 mg injection: Each pre-filled syringe contains Tirzepatide INN 5 mg in 0.5 ml solution for Injection.
Tirzema™ 7.5 mg injection: Each pre-filled syringe contains Tirzepatide INN 7.5 mg in 0.5 ml solution for Injection.

Description

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. It selectively binds to and activates both the GIP and GLP-1 receptors, the targets for native GIP and GLP-1. It enhances first and second-phase insulin secretion and reduces glucagon levels, both in a glucose dependent manner.

Indications

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

Dosage & Administration

The recommended starting dosage is 2.5 mg injected subcutaneously once weekly. The 2.5 mg dosage is for treatment initiation and is not intended for glycemic control. After 4 weeks, increase the dosage 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. The maximum dosage is 15 mg injected subcutaneously once weekly. Administer Tirzepatide once weekly, any time of day, with or without meals. Inject it 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 it 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. The day of weekly administration can be changed, if necessary, as long as the time between the two doses is at least 3 days (72 hours).

Contraindications

Personal or family history of medullary thyroid carcinoma (MTC) or in patients with multiple endocrine neoplasia syndrome type 2 (MEN 2). Hypersensitivity to tirzepatide or any of the excipients.

Warnings and Precaution

Risk of Thyroid C-cell Tumors: Counsel patients regarding the potential risk for MTC (Medullary Thyroid Carcinoma) and inform them of symptoms of thyroid tumors.
Pancreatitis: After initiation, observe patients carefully for signs and symptoms of pancreatitis. If pancreatitis is suspected, discontinue Tirzepatide and initiate appropriate management.
Hypoglycemia: The risk of hypoglycemia may be lowered by a reduction in the dose of sulfonylurea (or other concomitantly administered insulin secretagogue) or insulin.
Hypersensitivity reactions: If hypersensitivity reactions occur, discontinue use of Tirzepatide; treat promptly per standard of care and monitor until signs and symptoms resolve.
Acute Kidney Injury: Monitoring of renal function is needed when initiating or escalating doses in patients with renal impairment.
Severe Gastrointestinal Disease: Not recommended in these patients.
Diabetic Retinopathy: Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy.
Acute Gallbladder Disease: If cholelithiasis is suspected, gallbladder diagnostic studies and appropriate clinical follow-up are indicated.

Adverse Reaction: The most common adverse reactions are: nausea, diarrhoea, decreased appetite, vomiting, constipation, dyspepsia and abdominal pain.

Drug Interaction

Consider reducing the dose of concomitantly administered insulin secretagogues (e.g. sulfonylureas) or insulin to reduce the risk of hypoglycemia. Tirzepatide delays gastric emptying and thereby has the potential to impact the absorption of concomitantly administered oral medications. Monitor patients on oral medications dependent on threshold concentrations for efficacy and those with a narrow therapeutic index (e.g. warfarin) when concomitantly administered. Advise patients using oral hormonal contraceptives to switch to a nonoral contraceptive method or add a barrier method of contraception for 4 weeks after initiation and for 4 weeks after each dose escalation with it. Hormonal contraceptives that are not administered orally should not be affected.

Special Populations

Pediatric and Geriatric Use: Safety and effectiveness of Tirzepatide have not been established in patients under 18 years of age. No dose adjustment is required based on age.
Renal impairment: No dose adjustment is required for patients with renal impairment.
Hepatic impairment: No dose adjustment is required for patients with hepatic impairment.

Pregnancy and 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.

Overdose

Appropriate supportive treatment should be initiated according to the patient's clinical signs and symptoms.

Storage

Store at 2°C to 8°C (in a refrigerator). Do not freeze. Keep away from light and out of the reach of children.

Commercial Pack

Tirzema™ 2.5 mg injection: Each box contains 1 pre-filled syringe of Tirzepatide 2.5 mg Injection.
Tirzema™ 5 mg injection: Each box contains 1 pre-filled syringe of Tirzepatide 5 mg Injection.
Tirzema™ 7.5 mg injection: Each box contains 1 pre-filled syringe of Tirzepatide 7.5 mg Injection.

Manufactured by
Incepta Pharmaceuticals Ltd
Dhamrai Unit, Dhaka, Bangladesh