

Tirzepatide INN

COMPOSITION

Tirzepatide 2.5: Each pre-filled syringe contains 0.5 ml sterile solution of Tirzepatide INN 2.5 mg.

Tirzepatide 5: Each pre-filled syringe contains 0.5 ml sterile solution of Tirzepatide INN 5 mg.

Tirzepatide 7.5: Each pre-filled syringe contains 0.5 ml sterile solution of Tirzepatide INN 7.5 mg.

PHARMACOLOGY

Tirzepatide is a GIP (Glucose-Dependent Insulinotropic Polypeptide) receptor and GLP-1 (Glucagon Like Peptide-1) receptor agonist. It is an amino-acid sequence including a C20 fatty diacid 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.

INDICATION

It is indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients ≥ 10 years of age with type 2 diabetes mellitus.

It is also indicated in followings in combination with a reduced-calorie diet and increased physical activity:

- To reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition.
- To treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity.

Limitations of Use:

- Coadministration with other tirzepatide-containing products or with any GLP-1 receptor agonist is not recommended.

DOSAGE AND ADMINISTRATION

To improve glycemic control, the recommended starting dosage 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. To reduce excess body weight and maintain weight reduction long term in adults and to treat obstructive sleep apnea (OSA), the recommended starting dosage is 2.5 mg injected subcutaneously once weekly for 4 weeks. Increase the dosage in 2.5 mg increments after at least 4 weeks until recommended maintenance dosage is achieved. Consider treatment response and tolerability when selecting the maintenance dosage. Recommended maintenance dosage for weight reduction and for long-term maintenance is 5 mg, 10 mg, or 15 mg injected subcutaneously once weekly and for obstructive sleep apnea is 10 mg or 15 mg injected subcutaneously once weekly.

Maximum recommended dosage:

- Adults: 15 mg subcutaneously once weekly.
- Pediatric patients ≥ 10 years of age: 10 mg subcutaneously once weekly.

Administration Instructions:

-Inspect visually before use; It should appear clear and colorless to slightly yellow. Do not use if particulate matter or discoloration is seen.

-Administer once weekly at any time of day, with or without meals.

-Inject subcutaneously in the abdomen, thigh, or another person should inject in the back of the 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.

CONTRAINDICATION

It is contraindicated if patients with known hypersensitivity to tirzepatide or any other components of this product. Patients with a personal or family history of medullary thyroid carcinoma (MTC) or in patients with multiple endocrine neoplasia type 2 (MEN 2).

WARNING & PRECAUTION

It should be administered with caution in the following cases:

- Severe Gastrointestinal adverse reactions: Use has been associated with gastrointestinal adverse reactions, sometimes severe. It is not recommended in patients with severe gastroparesis.
- Acute Kidney Injury Due to Volume Depletion: Monitor renal function in patients reporting adverse reactions.
- Acute Gallbladder Disease: If cholecystitis is suspected, gallbladder studies and clinical follow-up are indicated.
- Acute Pancreatitis: Discontinue if pancreatitis is suspected.
- Hypoglycemia: Concomitant use with insulin or an insulin secretagogue may increase the risk of hypoglycemia. Reducing dose of insulin or insulin secretagogue may be necessary. Inform all patients of the risk of hypoglycemia.
- Diabetic Retinopathy: Monitor patients.
- Suicidal Behavior and Ideation: Monitor for depression or suicidal thoughts. Discontinue it if symptoms develop.
- Pulmonary Aspiration During General Anesthesia or Deep Sedation: Instruct patients to inform healthcare providers of any planned surgeries or procedures.
- 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.

SIDE EFFECT

The most common side effects $\geq 5\%$ are nausea, diarrhea, vomiting, constipation, abdominal pain, dyspepsia, injection site reactions, fatigue, hypersensitivity reactions, eructation, hair loss, gastroesophageal reflux disease.

USE IN PREGNANCY & LACTATION

May cause fetal harm in pregnancy. When pregnancy is recognized, discontinue it. During breast feeding consider the based-on risk-benefit of mother and infant.

USE IN CHILDREN AND ADOLESCENTS

The safety and effectiveness of Tirzepatide have not been established in pediatric patients less than 10 years of age.

DRUG INTERACTION

Concomitant use with insulin or an insulin secretagogue may increase the risk of hypoglycemia, including severe hypoglycemia. Reducing dose of insulin or insulin secretagogue may be necessary.

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

OVERDOSAGE

In case of overdosage, appropriate supportive treatment should be initiated according to the patient's clinical signs and symptoms. A period of observation and treatment for these symptoms may be necessary, taking into account the half-life of it of approximately 5 days.

STORAGE

Store in refrigerator at 2°C to 8°C temperature. Protect from light. Do not freeze. Do not use it if frozen. Keep out of the reach of children.

HOW SUPPLIED

Tirzepatide 2.5: Each box contains 1 pre-filled syringe containing 0.5 ml sterile solution of Tirzepatide INN 2.5 mg, a leaflet in Alu-PVC blister and an alcohol pad.

Tirzepatide 5: Each box contains 1 pre-filled syringe containing 0.5 ml sterile solution of Tirzepatide INN 5 mg, a leaflet in Alu-PVC blister and an alcohol pad.

Tirzepatide 7.5: Each box contains 1 pre-filled syringe containing 0.5 ml sterile solution of Tirzepatide INN 7.5 mg, a leaflet in Alu-PVC blister and an alcohol pad.

Manufactured by:

NIPRO JMI Pharma Ltd.

Chauddagram, Cumilla, Bangladesh.