Wikijet

Tirzepatide INN

Composition:

Wikijet 2.5 mg/0.5 ml solution for injection in pre-filled syringe: Each pre-filled syringe contains Tirzepatide INN 2.5 mg in 0.5 ml solution for injection.

Wikijet 5 mg/0.5 ml solution for injection in pre-filled syringe: Each pre-filled syringe contains Tirzepatide INN 5 mg in 0.5 ml solution for injection.

Pharmacology:

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 lowers fasting and postprandial glucose concentration, decreases food intake, and reduces body weight in patients with type 2 diabetes mellitus.

Indications:

Wikijet 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.
- as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adult patients 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, type 2 diabetes mellitus or dyslipidemia).

Dosage & Administration:

The recommended starting dose of **Wikijet** is 2.5 mg injected subcutaneously once weekly for 4 weeks. The 2.5 mg dosage is for treatment initiation and is not intended for glycemic control. After 4 weeks on the 2.5 mg dose, the dose is increased 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 recommended dosage is 15 mg once weekly. **Wikijet** is administered once weekly, on the same day each week, at any time of the day, with or without meals. **Wikijet** is to be injected subcutaneously in the abdomen, thigh or in upper arm. The day of weekly administration can be changed if necessary as long as the time between two doses is at least 3 days (72 hours).

Contraindication:

Tirzepatide is contraindicated in patients with known hypersensitivity to Tirzepatide or to any of the components. Also contraindicated in patients with a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

Warning & Precaution:

Pancreatitis: Has been reported in clinical trials. Discontinue promptly if pancreatitis is suspected. Do not restart if pancreatitis is confirmed. 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 of tirzepatide may be associated with gastrointestinal adverse reactions, sometimes severe. Tirzepatide 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: Patients with a history of diabetic retinopathy should be monitored. Risk of Thyroid C-cell Tumors.

Side Effects:

Sometimes hypoglycemia can occur when used with sulfonylurea. The most frequent adverse reactions are gastrointestinal disorder, nausea, diarrhea, vomiting, abdominal pain and constipation. Beside these injection site reactions may occur.

Use in special population:

Pregnancy: Tirzepatide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. 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.

Lactation: There are no data on the presence of Tirzepatide in human milk, the effects on the breastfed infant, or the effects on milk production.

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

Hepatic Impairment: No dose adjustment of Tirzepatide is recommended for patients with hepatic impairment.

Renal Impairment: No dose adjustment of Tirzepatide is recommended for patients with renal impairment.

Drug Interaction:

Oral Medications: Tirzepatide causes a delay of gastric emptying, and thereby has the potential to impact the absorption of other oral medications.

Overdose:

In the event of overdose, appropriate supportive treatment should be initiated according to the patient's clinical signs and symptoms. A prolonged period of observation and treatment for these symptoms may be necessary.

Storage:

Store in a refrigerator at 2°C-8°C. Keep out of the reach of children.

Packing:

Wikijet 2.5 mg/0.5 ml solution for injection in pre-filled syringe: Each box contains 1 pre-filled syringe of Tirzepatide 2.5 mg/0.5 ml injection.

Wikijet 5 mg/0.5 ml solution for injection in pre-filled syringe: Each box contains 1 pre-filled syringe of Tirzepatide 5 mg/0.5 ml injection.

Manufactured by:
ARISTOPHARMA LTD.
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