

# Duotir®

Tirzepatide INN

## Description

Duotir® is the preparation of Tirzepatide, a once-weekly GIP receptor and GLP-1 receptor agonist. It is a 39-amino-acid modified peptide based on the GIP sequence.

## 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.

## Pharmacokinetics

**Absorption:** Absolute bioavailability of Tirzepatide is 80%. Maximum concentration of Tirzepatide is reached 8 to 72 hours post dose.

**Distribution:** The apparent steady-state volume of distribution was eliminated to be 10.3L & Plasma protein binding is 99%

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

**Elimination:** Elimination half-life of Tirzepatide was estimated to be 5 days.

## Composition

**Duotir® 2.5 mg SC injection:** Each pre-filled syringe contains Tirzepatide INN 2.5 mg in 0.5 ml sterile solution for injection.

**Duotir® 5 mg SC injection:** Each pre-filled syringe contains Tirzepatide INN 5 mg in 0.5 ml sterile solution for injection.

**Duotir® 7.5 mg SC injection:** Each pre-filled syringe contains Tirzepatide INN 7.5 mg in 0.5 ml sterile solution for injection.

## Indications

Duotir® is indicated as an adjunct to diet and exercise to 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

- It has not been studied in patients with a history of pancreatitis
- It is not indicated for use in patients with type 1 diabetes mellitus

## Dosage and Administration

**Dosage:** ♦ The recommended starting dosage of Duotir® 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 of Duotir® is 15 mg injected subcutaneously once weekly

♦ If a dose is missed, instruct patients to administer Duotir® 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)

**Administration:** ♦ Administer Duotir® once weekly, any time of day, with or without meals

♦ Inject Duotir® subcutaneously in the abdomen, thigh, or upper arm. Rotate injection sites with each dose. When using Duotir® with insulin, administer as separate injections and never mix. It is acceptable to inject Duotir® and insulin in the same body region, but the injections should not be adjacent to each other

## Contraindications

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

## Side Effects

The most common side effects are gastrointestinal disorder, nausea, diarrhea, vomiting, abdominal pain and constipation.

## Use in pregnancy & lactation

**Pregnancy:** 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.

**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.

## Precautions

• **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 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 interactions

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.

## Overdose

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 Tirzepatide, approximately 5 days.

## Storage

Keep out of the reach of children. Store in a refrigerator at 2°C to 8°C. Do not freeze & do not use if it has been frozen.

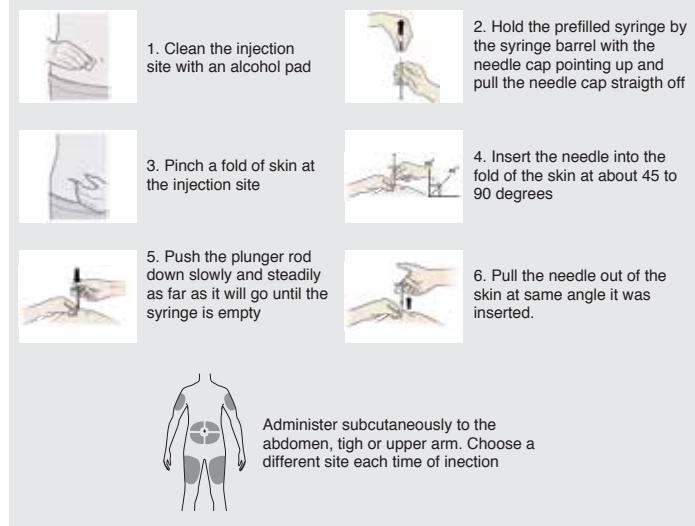
## Packaging

**Duotir® 2.5 mg SC injection:** Each carton contains 1 pre-filled syringe containing 0.5 ml sterile solution of Tirzepatide INN 2.5 mg in Alu-PVC blister pack and 1 complimentary alcohol pad.

**Duotir® 5 mg SC injection:** Each carton contains 1 pre-filled syringe containing 0.5 ml sterile solution of Tirzepatide INN 5 mg in Alu-PVC blister pack and 1 complimentary alcohol pad.

**Duotir® 7.5 mg SC injection:** Each carton contains 1 pre-filled syringe containing 0.5 ml sterile solution of Tirzepatide INN 7.5 mg in Alu-PVC blister pack and 1 complimentary alcohol pad.

## Administration Instructions



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