**Tirzepatide** (MOUNJARO/ZEPBOUND®) **injection, solution
Eli Lilly and Company**

**INDICATIONS AND USAGE**

* **Tirzepatide** (MOUNJARO/ZEPBOUND®) is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults 18 years and older, with an initial body mass index (BMI) of:
* 30 kg/m2 or greater (obesity) or
* 27 kg/m2 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).
* Limitations of Use:
* Coadministration with other tirzepatide-containing products or any GLP-1 receptor agonist is not recommended. (Example: Ozempic, Wegovy, Semaglutide)
* The safety and efficacy of coadministration with other products for weight management have not been established.
* It has not been studied in patients with a history of pancreatitis.

**DOSAGE AND ADMINISTRATION**

* The recommended starting dosage is 2.5 mg injected subcutaneously once weekly.
* After 4 weeks, increase to 5 mg injected subcutaneously once weekly.
* Increase the dosage in 2.5 mg increments after at least 4 weeks on the current dose.
* The recommended maintenance dosages are 5 mg, 10 mg, or 15 mg injected subcutaneously once weekly.
* Consider treatment response and tolerability when selecting the maintenance dosage.
* 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.

**CONTRAINDICATIONS**

* Personal or family history of **medullary thyroid carcinoma** or in patients with Multiple Endocrine Neoplasia syndrome type 2
* **Pregnancy** (for the next 60 days)
* History of **Pancreatitis**
* Known serious hypersensitivity to tirzepatide.

**WARNINGS AND PRECAUTIONS**

* *Severe Gastrointestinal Disease:* Use has been associated with gastrointestinal adverse reactions, sometimes severe. Has not been studied in patients with severe gastrointestinal disease and is not recommended in these patients.
* *Acute Kidney Injury:* Monitor renal function in patients reporting adverse reactions like vomiting that could lead to volume depletion (dehydration).
* *Acute Gallbladder Disease:* Has been reported in clinical trials. If cholecystitis is suspected, gallbladder studies and clinical follow-up are indicated.
* *Acute Pancreatitis:* Has been reported in clinical trials. Discontinue promptly if pancreatitis is suspected. Do not restart if pancreatitis is confirmed.
* *Hypersensitivity Reactions:* Serious hypersensitivity reactions (e.g., anaphylaxis, angioedema) have been reported post-marketing with tirzepatide. If suspected, advise patients to promptly seek medical attention and discontinue **Tripeptide** (MOUNJARO/ZEPBOUND®) .
* *Hypoglycemia:* 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. Inform all patients of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia.
* *Diabetic Retinopathy Complications in Patients with Type 2 Diabetes Mellitus:* 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.
* *Suicidal Behavior and Ideation:* Monitor for depression or suicidal thoughts. Discontinue if symptoms develop.

**ADVERSE REACTIONS**

The most common adverse reactions reported in ≥5% of patients are:

* nausea, diarrhea, vomiting, constipation, abdominal pain, dyspepsia, injection site reactions, fatigue, hypersensitivity reactions, eructation, hair loss, gastroesophageal reflux disease.

**To report SUSPECTED ADVERSE REACTIONS, contact Eli Lilly and Company at 1-800-LillyRx (1-800-545-5979) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

**DRUG INTERACTIONS**

**Tirzepatide** (MOUNJARO/ZEPBOUND®)  delays gastric emptying and has the potential to impact the absorption of concomitantly administered oral medications.

**USE IN SPECIFIC POPULATIONS**

* ***Pregnancy****:* May cause fetal harm. When pregnancy is recognized, discontinue **Tirzepatide** (MOUNJARO/ZEPBOUND®). *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.

**BOXED WARNING**

**WARNING: RISK OF THYROID C-CELL TUMORS**

* **In rats, tirzepatide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Tirzepatide** (MOUNJARO/ZEPBOUND®)  **causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of tirzepatide-induced rodent thyroid C-cell tumors has not been determined.**
* **Tirzepatide** (MOUNJARO/ZEPBOUND®)  **is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Tirzepatide and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Tirzepatide** (MOUNJARO/ZEPBOUND®)**.**