

New Drug Approval: Mounjaro™ (tirzepatide) injection

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

Mechanism: Novel dual glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1) receptor agonist

GIP Mechanism: Insulinotropic in hyperglycemic state and glucagonotropic in euglycemic or hypoglycemic state

Formulation: Once-weekly auto-injection available in 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg and 15 mg doses titrated in 4-week intervals



Limitations of Use:

- Has not been studied in patients with a history of pancreatitis
- Not indicated for use in patients with type 1 diabetes
- Avoid concurrent use with GLP-1 receptor agonists (Category X interaction)

Side Effects (*prevalence* $\geq 5\%$): nausea, diarrhea, decreased appetite, vomiting, constipation, dyspepsia, abdominal pain

Contraindications: Personal or family history of medullary thyroid carcinoma or in patients with multiple endocrine neoplasia syndrome type 2 (MEN 2)

SURPASS-1 Study:

- Background: 40-week study comparing the efficacy and safety of Mounjaro 5 mg (N=121), 10 mg (N=121), and 15 mg (N=120) as monotherapy to placebo (N=113) in adults with type 2 diabetes
- Primary Outcome: From a baseline A1C of 7.9%, Mounjaro reduced participants' A1C by a mean of 1.8% (5 mg) and 1.7% (10 mg and 15 mg) compared to 0.1% for placebo
- Secondary Outcome: From a baseline weight of 189 lb, Mounjaro reduced participants' weight by a mean of 14 lb (5 mg), 15 lb (10 mg), and 17 lb (15 mg) compared to 2 lb for placebo

SURPASS-CVOT (*in-progress*): Will compare tirzepatide versus dulaglutide on major cardiovascular events in participants with type 2 diabetes