

Mounjaro[™] (tirzepatide) – New drug approval

- On May 13, 2022, the [FDA announced](#) the approval of [Eli Lilly's Mounjaro \(tirzepatide\)](#), as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM).
 - Mounjaro has not been studied in patients with a history of pancreatitis.
 - Mounjaro is not indicated for use in patients with type 1 diabetes mellitus.
- Mounjaro is a novel dual glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1) receptor agonist. Mounjaro enhances first- and second-phase insulin secretion, and reduces glucagon levels, both in a glucose-dependent manner.
- The efficacy of Mounjaro was established in five studies. In these trials, Mounjaro was studied as monotherapy (SURPASS-1); as an add-on to metformin, sulfonylureas, and/or sodium-glucose co-transporter 2 inhibitors (SGLT2 inhibitors) (SURPASS-2, -3, and -4); and in combination with basal insulin with or without metformin (SURPASS-5). In these studies, Mounjaro (5 mg, 10 mg, and 15 mg given subcutaneously [SC] once weekly) was compared with placebo, [Ozempic[®] \(semaglutide\)](#) 1 mg, [Tresiba[®] \(insulin degludec\)](#), and/or insulin glargine.
 - On average, patients randomized to receive the maximum recommended dose of Mounjaro (15 mg) had lowering of their HbA1c level by 1.6% more than placebo when used as stand-alone therapy, and 1.5% more than placebo when used in combination with a long-acting insulin.
 - In studies comparing Mounjaro to other diabetes medications, patients who received the maximum recommended dose of Mounjaro had lowering of their HbA1c by 0.5% more than Ozempic 1 mg ($p < 0.001$), 0.9% more than Tresiba ($p < 0.001$), and 1.0% more than insulin glargine ($p < 0.001$).
- Mounjaro carries a boxed warning for risk of thyroid C-cell tumors.
- Mounjaro is contraindicated in patients with:
 - A personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2.
 - Known serious hypersensitivity to tirzepatide or any of the excipients in Mounjaro.
- Additional warnings and precautions for Mounjaro include pancreatitis; hypoglycemia with concomitant use of insulin secretagogues or insulin; hypersensitivity reactions; acute kidney injury; severe gastrointestinal disease; diabetic retinopathy complications in patients with a history of diabetic retinopathy; and acute gallbladder disease.
- The most common adverse reactions ($\geq 5\%$) with Mounjaro use were nausea, diarrhea, decreased appetite, vomiting, constipation, dyspepsia, and abdominal pain.
- The recommended starting dosage of Mounjaro is 2.5 mg injected SC once weekly. The 2.5 mg dosage is for treatment initiation and is not intended for glycemic control. After 4 weeks, the dosage should be increased to 5 mg injected SC once weekly. If additional glycemic control is needed, the dosage should be increased in 2.5 mg increments after at least 4 weeks on the current dose.
 - The maximum dosage is 15 mg injected SC once weekly.

- Eli Lilly plans to launch Mounjaro in the coming weeks. Mounjaro will be available as 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, or 15 mg per 0.5 mL single-dose pens.



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