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Overview

Mounjaro and Ozempic are medicines approved to help control blood sugar levels in adults with type 2 diabetes. Both drugs can also lead to significant weight loss, an off-label use. In one study, Mounjaro led to at least a 5% weight loss within one year in 81.8% of adults compared to 66.5% of those using Ozempic.

Ozempic is also approved to lower the risk of a major cardiovascular event (like a heart attack or stroke) in patients with type 2 diabetes, as well as to reduce the risk of worsening kidney disease and heart-related death in patients with type 2 diabetes. Mounjaro has not yet received these indications, although studies are ongoing.

The brand names Mounjaro (tirzepatide) and Ozempic (semaglutide) may lead to significant weight loss, but are not yet specifically approved by the FDA for this use. But your healthcare provider might prescribe one of these medicines "off-label" for weight loss, meaning it's prescribed for a generally accepted use, but not yet specifically approved by the FDA or listed in package labeling.

If weight loss is your main goal, you have other options, too: <u>Wegovy</u> (semaglutide) and <u>Zepbound</u> (tirzepatide) are the brand name products for these drugs that are approved for long-term weight loss.

Gastrointestinal side effects, like nausea and diarrhea, are the most common side effects seen with these drugs. Slowly increasing the dose, as directed by your healthcare provider, may help you more effectively manage the stomach side effects.

Both <u>Mounjaro</u> and <u>Ozempic</u> are given as a weekly subcutaneous injection in the abdomen, thigh, or upper arm. You, or a caregiver, can learn to give these injections at home. The Rybelsus brand of semaglutide is also available as an oral tablet for type 2 diabetes.

These medicines are expensive if you are fully paying out-of-pocket as no generic option is available on the U.S. market. Insurance, discount coupons, copay cards, and manufacturers financial assistance may help lower your out-of-pocket costs, if you qualify.

Do Mounjaro and Ozempic both lower A1C?

Yes, both drugs can also help you reach your A1C goal, which can prevent diabetes complications like heart and blood vessel disease, nerve damage, kidney failure and vision loss. With treatment, your blood sugar levels may start to decline right away, but it can take 2 to 3 months to reach your target A1C goal.

A1C is a simple blood test that shows the average amount of sugar (glucose) in your blood over the past 2 to 3 months, giving you and your doctor a better idea of long-term control of your diabetes.

People with type 2 diabetes usually have an A1C blood test twice per year. For most, but not all people, the goal is less than 7%. Your healthcare provider can inform you of your target A1C goal.

Are Mounjaro and Ozempic in the same drug class?

Mounjaro and Ozempic are both in the class of drugs known as incretin mimetics but have some differences. Mounjaro acts on both GIP and GLP-1 receptors, while Ozempic acts only on GLP-1 receptors; however, both drugs are effective treatments for type 2 diabetes and lead to weight loss.

- Mounjaro (tirzepatide), from Eli Lilly, is a dual-acting GIP (glucose-dependent insulinotropic polypeptide) and GLP-1 (glucagon-like peptide-1) receptor agonist. GIP and GLP-1 are both natural incretin hormones. Mounjaro lowers fasting and postprandial glucose concentration, decreases food intake, and reduces body weight in patients with type 2 diabetes mellitus.
- Ozempic (semaglutide), from Novo Nordisk, is a GLP-1 (glucagon-like peptide-1) receptor agonist, and not work at the GIP receptor like Mounjaro. It binds to GLP-1 receptors and stimulates insulin release from the pancreas when needed and lowers glucose (sugar) production. It slows down how fast food travels through your digestive tract. This can help you feel fuller for longer, reduce how much you eat, and lead to weight loss.

These medicines should not be used together or with any other GLP-1 or GIP receptor agonists.

How are they given?

Both Mounjaro and Ozempic are given as weekly injections under the skin (subcutaneously) in the stomach area (abdomen), thigh or upper arm. You, or a caregiver, can learn to give these injections at home using an injector pen. For both drugs, you will start with low doses to help prevent common stomach side effects like nausea, vomiting, decreased appetite or diarrhea. Other common stomach side effects may include constipation, indigestion, and stomach (abdominal) pain.

Mounjaro

- The recommended starting dose of Mounjaro is 2.5 mg subcutaneously once weekly, increasing to 5 mg once weekly after 4 weeks. The 2.5 mg dosage is for treatment initiation and is not intended for glycemic control.
- If additional glycemic control is needed after at least 4 weeks, your doctor may increase your dose. The maximum dosage is 15 mg subcutaneously once weekly.

Ozempic

- Blood sugar control in type 2 diabetes: The recommended starting dose of Ozempic is 0.25 mg given subcutaneously once weekly. The 0.25 mg dosage is intended for treatment initiation and is not effective for glycemic control. After 4 weeks, the dose is increased to 0.5 mg once weekly. If additional glycemic control is needed after at least 4 weeks, your doctor may increase your dose. The recommended maintenance dosage is 0.5 mg, 1 mg, or 2 mg, injected subcutaneously once weekly, based on glycemic control. The maximum recommended dose is 2 mg weekly
- Chronic kidney disease and type 2 diabetes: To reduce the risk of worsening kidney disease and cardiovascular death in patients with type 2 diabetes, initiate treatment on the 0.25 mg dosage for 4 weeks, then increase to 0.5 mg once weekly after 4 weeks on the

lower dose. The final recommended maintenance dosage is 1 mg, given subcutaneously once weekly.

Which is more effective in type 2 diabetes - Mounjaro or Ozempic?

Phase 3 SURPASS-2 study

Mounjaro was compared to semaglutide (Ozempic) in the 40-week, Phase 3 SURPASS-2 study with over 1,870 participants. Researchers sought to see how these drugs affected A1C reduction. A key secondary endpoint was the amount of weight lost. Neither brand name Mounjaro or Ozempic are approved for weight loss at this time, but in patients with type 2 diabetes, they may lead to some weight reduction. Wegovy (semaglutide) and Zepbound (tirzepatide) are the brand name products now approved by the FDA for weight loss.

Mounjaro 5 mg, 10 mg, and 15 mg injections were compared to semaglutide (Ozempic) 1 mg injections in adults with type 2 diabetes whose blood sugars were not controlled with 1,500 mg/day of metformin alone. Patients in the study had an A1c of 8.3% and a weight of 94.1 kg (207 lb) at the beginning of the study.

- Mounjaro reduced the A1C by 2% to 2.3% compared to a 1.9% reduction for participants in the semaglutide (Ozempic) 1 mg group.
- Mounjaro led to weight loss of 7.7 kg (17 lb) to 11.4 kg (25 lb), on average, compared to 5.9 kg (13 lb) for semaglutide (Ozempic).
- Of note, Ozempic is now approved in a higher 2 mg dose, and effectiveness compared to Mounjaro with this higher dose may vary. The 2 mg dose was approved by the FDA in March 2022.

Meta-analysis: EASD Abstract

In 2023, the results of a network meta-analysis was reported by Karagiannis and colleagues at the European Association for the Study of Diabetes (EASD) meeting that directly compared the effectiveness and safety of tirzepatide to that of subcutaneous semaglutide in people with type 2 diabetes. This study did include the higher 2 mg dose of semaglutide (Ozempic).

Researchers included 22 randomized controlled trials with 18,472 participants. Studies included a maintenance dose of tirzepatide 5, 10, or 15 mg once-weekly or subcutaneous semaglutide 0.5, 1, or 2 mg once-weekly for at least 12 weeks.

- Tirzepatide 15 mg (the highest available dose) was the most effective in lowering A1c versus placebo (mean difference [MD], -2%, 95% CI -2.16 to -1.84), followed by tirzepatide 10 mg (MD -1.86%, 95% CI -2.02 to -1.84) and semaglutide 2 mg (MD, 95% CI -1.62%, -1.96 to -1.28).
- Each of the three tirzepatide doses reduced A1c more than the respective semaglutide doses.
- Tirzepatide 10 and 15 mg doses were more effective in lowering body weight than either the 1 or 2 mg dose of semaglutide, while the tirzepatide 5 mg dose was more effective than semaglutide 0.5 and 1 mg. Tirzepatide was also more effective than placebo in reducing body weight.

- All doses of both drugs increased the risk of stomach side effects compared to placebo. The highest dose of tirzepatide (Mounjaro) had the highest risk for nausea (risk ratio [RR], 3.57), vomiting (RR, 4.35), and diarrhea (RR, 2.04).
- Tirzepatide 15 mg was associated with increased risk for vomiting versus the 0.5 and 1 mg dose of semaglutide.
- There was no difference between tirzepatide, semaglutide and placebo with regards to risk for serious adverse events.

Overall, researchers found that in people with type 2 diabetes, tirzepatide 5, 10, and 15 mg subcutaneous injection doses were more effective in lowering A1c compared to semaglutide 0.5, 1, and 2 mg, respectively, but was associated with more stomach side effects.

Which is more effective for weight loss - Mounjaro or Ozempic?

Studies are looking at weight loss comparisons between Mounjaro and Ozempic, even though both products are only approved for type 2 diabetes at this time.

In a July 2024 retrospective, electronic health record (EHR) study in 41,222 adults with overweight or obesity treated for type 2 diabetes, 81.8% of people receiving tirzepatide (Mounjaro) lost at least 5% of their weight within one year compared to 66.5% of those using semaglutide (Ozempic), a significant difference (which means it did not just happen by chance).

At 12 months, the difference in weight loss between Mounjaro and Ozempic was 6.9%, favoring Mounjaro. Larger weight reductions occurred in groups without type 2 diabetes, as seen in other studies.

However, over 50% of participants in each group discontinued treatment. Additional study is needed to determine the reasons which may have been due to drug shortages, side effects or costs.

No differences were seen in rates of moderate-to-severe digestive tract (gastrointestinal) side effects, including bowel obstruction, cholecystitis (gallbladder inflammation), cholelithiasis (gallstones), gastroenteritis (stomach / intestine infection), gastroparesis (delayed stomach emptying) and pancreatitis (inflammation of the pancreas).

Common, more mild side effects such as nausea and vomiting were not included in the study data as it may have been hard to reliably gather this data from an EHR, according to researchers.

A Phase 3b trial (SURMOUNT-5, NCT05822830) directly comparing tirzepatide to semaglutide in patients without type 2 diabetes, but who have obesity or overweight with weight related comorbidities, is currently ongoing with results expected towards the end of 2024. The study is being conducted by Eli Lilly and Co.

How do side effects compare between Mounjaro and Ozempic?

Gastrointestinal (digestive tract) side effects are the most common side effects for both Mounjaro and Ozempic, and incretin mimetics in general. Stomach side effects are most frequent when doses are first initiated. Slowly increasing the dose, as recommended by your healthcare provider, may help to reduce stomach side effects.

Rates of side effects cannot be compared outside of direct comparative clinical studies as patient populations, doses and study designs may differ.

Side Effects: Mounjaro

In Mounjaro studies, the most commonly reported side effects, compared to a placebo (an inactive agent) are:

- Nausea: 12% to 18% (vs. 4% on placebo)
- Diarrhea: 12% to 17% (vs. 9% on placebo)
- Decreased appetite: 5% to 11% (vs. 1% on placebo)
- Vomiting: 5% to 9% (vs. 2% on placebo)
- Constipation: 6% to 7% (vs. 1% on placebo)
- Heartburn (dyspepsia): 5% to 8% (vs. 3% on placebo)
- Stomach (abdominal) pain: 5% to 6% (vs. 4% on placebo)

Overall, stomach side effects occurred in 37% to 44% of Mounjaro-treated patients (compared to 20% of patients on a placebo). In addition, 3% to 6.6% of patients receiving Mounjaro stopped treatment due to gastrointestinal side effects (like nausea, vomiting, and/or diarrhea) compared to placebo (0.4%). Most reports of nausea, vomiting, and/or diarrhea occurred during dose escalation at the start of treatment and decreased over time.

Other reported side effects for Mounjaro included: hypoglycemia (low blood sugar), increased heart rate, allergic reactions, injection site reactions, acute gallbladder disease, and increases in amylase and lipase (pancreas enzymes).

Side Effects: Ozempic

The most common side effects with Ozempic are:

- Nausea: 16% to 20% (vs. 6% on placebo)
- Diarrhea: 8.5% to 8.8% (vs. 1.9% on placebo)
- Vomiting: 5% to 9.2% (vs. 2.3% on placebo)
- Constipation: 3.1% to 5% (vs. 1.5% on placebo)
- Heartburn (dyspepsia): 2.7% to 3.5% (vs. 1.9% on placebo)
- Stomach (abdominal) pain: 5.7% to 7.3% (vs. 4.6% on placebo)

Overall, stomach side effects occurred in 33% to 36% of Ozempic-treated patients (compared to 15% of patients on a placebo). In addition, 3.1% to 3.8% of patients receiving Ozempic stopped treatment due to gastrointestinal side effects compared to 0.4% of the placebo group.

Other reported side effects for Ozempic included: hypoglycemia (low blood sugar), injection site reactions, elevated amylase and lipase (pancreas enzymes), cholelithiasis (gallstones), increases in heart rate, and fatigue, dysgeusia (altered taste), allergic reactions and dizziness.

The labeling for both Mounjaro and Ozempic carry **Boxed Warnings** for possible thyroid tumors, including cancer, which has been seen in animal studies. Do not use these products if:

- you or your family has a history of medullary thyroid carcinoma (MTC), or
- if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- Symptoms of thyroid tumors can include a mass in the neck, dysphagia (trouble swallowing, dyspnea (shortness of breath), or persistent hoarseness. Discuss this further with your healthcare provider.

lleus (intestinal blockage) risk

In Sept. 2023, the FDA updated the side effects for Ozempic (semaglutide) to emphasize that an ileus, an intestinal blockage, has been reported as a possible side effect. In addition to Ozempic, this warning also exists for Mounjaro (tirzepatide) and other semaglutide products Wegovy and Rybelsus.

An ileus is an intestinal blockage that results in the failure of the intestinal contents to pass through the gut, but it doesn't involve a physical blockage. In paralytic ileus problems with the muscle or nerves found in the intestine interfere with normal muscle contractions

Because these side effects were voluntarily reported, the FDA cannot reliably determine how often this side effect occurs or if the drug actually caused the ileus. Speak to your doctor about your risk for this side effect.

Symptoms of an ileus can include:

- stomach area (abdominal) swelling
- fullness, gas in the stomach are
- stomach area pain / cramping
- breath odor
- constipation
- diarrhea
- inability to pass gas
- vomiting

Lung aspiration risk (food getting into your lungs)

In addition, GLP-1 agents like Ozempic or Mounjaro that slow down food passage through the stomach may rarely increase the risk of food or liquid getting into the lungs during surgery or other procedures that use anesthesia or deep sedation. Tell your healthcare provider that you use Ozempic, Mounjaro or any other incretiin mimetic drug before you are scheduled to have any procedure or surgery.

Comparing Mounjaro vs. Ozempic Prices

Mounjaro cost

The dose for one Mounjaro (tirzepatide) weekly injection ranges between 5 mg and 15 mg. The typical maintenance dose for Mounjaro is 5 mg per week injected subcutaneously (under the skin). Mounjaro single-dose pens are available in 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 and 15 mg doses. The maximum dosage is 15 mg subcutaneously once weekly.

- For example, the cost for a carton of four 5 mg Mounjaro single-dose pens (each pen delivers 5 mg per injection) is about \$1137. One carton should last a month. Prices will vary.
- All of the Mouniaro pen strengths are roughly the same price per carton.

Ozempic cost

The dose for one Ozempic (semaglutide) weekly injection ranges between 0.5 mg and 2 mg. The typical maintenance dose for Ozempic is 0.5 to 1 mg injected subcutaneously (under the skin) once a week. Ozempic injection pens are available in 2 mg, 4 mg and 8 mg per pen (multi-use, single patient pen). The maximum recommended dose of Ozempic is 2 mg weekly.

- For example, the cost for a 3 mL Ozempic pen that holds a total of 4 mg and delivers 1 mg per injection is about \$1051. If you use a 1 mg dose, this pen would last you for one month (one 1 mg dose per week for 4 weeks). Prices will vary. Each carton also comes with NovoFine Plus needles.
- All of the Ozempic pen strengths are about the same price.

This is not all the information you need to know about Mounjaro or Ozempic for safe and effective use and does not take the place of your doctor's directions. Review the full patient medication guide and discuss this information and any questions you have with your doctor or other health care provider.

How long does it take for Ozempic to work?

Your blood glucose (sugar) levels should start to fully decline within the first week after you start using Ozempic (semaglutide) at your regular dose. However, the full effect can take 8 weeks or longer, as this is a long-acting medication that is injected only once per week.

Key Points

- Your blood glucose (sugar) levels should start to fully decline within the first week after you start using Ozempic (semaglutide) at your regular maintenance dose.
- However, the full effect can take 8 weeks or longer, as this is a long-acting medication that
 is injected only once per week. You will start with lower doses for the first 4 weeks of
 treatment to help lower side effects, but this is not an effective dose to lower blood sugar
 over the long-term.
- Ozempic is administered once weekly, on the same day each week, and can be taken at any time of the day with or without meals
- Your results may be different from other patients, so check with your doctor if you have a concern about your blood sugar levels.

Most patients will start Ozempic treatment at the lower 0.25 mg dose injected once a week for 4 weeks. The 0.25 mg dose is not used as your final maintenance dose to lower your blood sugar. Starting with the lower dose initially may help you tolerate some of the side effects.

After 4 weeks at the 0.25 mg dose, your dose will usually be increased to 0.5 mg per week, then possibly to 1 mg per week, based on your response to treatment and how well you tolerated it

The manufacturer notes that it takes 4 to 5 weeks of once-weekly administration with Ozempic to reach steady state. Steady state is the time during which the concentration of the drug in the body stays consistent. In other words, steady state is when the rate of the drug going into your body is equal to the rate of drug elimination.

Although steady state levels are reached in 4 to 5 weeks, clinical effectiveness with Ozempic will vary from person to person and may take longer due to unique factors such as age, weight, amount of body fluid, additional medications you take, kidney or liver function, or your other medical conditions.

It may also take longer based on how quickly you can achieve your final maintenance dose. Your doctor knows your medical condition the best and can give you specific information on your overall response time to Ozempic.

Type 2 diabetes is long-term (chronic) disease and medications are used for maintenance treatment. The full beneficial effects of Ozempic on your heart require you to take your medication on a long-term basis. Your doctor may combine Ozempic with other diabetes medication to further reduce your blood sugar levels or for added benefits

Ozempic can also help protect your kidneys. The recommended maintenance dose to reduce the risk of worsening kidney disease and cardiovascular death in patients with type 2 diabetes and chronic kidney disease is 1 mg injected subcutaneously once per week. Increase the dosage to 1 mg once weekly slowly as directed by your healthcare provider to help avoid GI effects.

Do not stop taking your medication or adjust any doses without speaking to your doctor first.

What side effects are most likely with Ozempic?

The most common side effects reported in ≥5% of patients treated with Ozempic are:

- nausea (16% to 20%)
- vomiting (5% to 9%)
- diarrhea (8% to 9%)
- abdominal (stomach) pain (6% to 7%)
- constipation (3% to 5%)

Stomach side effects are most common when starting treatment but decrease over time in most patients.

The FDA updated the side effects in the label for Ozempic (semaglutide) to emphasize that an ileus, an intestinal blockage, has been reported as a possible side effect. Because this side effect was voluntarily reported, the FDA cannot reliably determine how often this side effect

occurs or if the drug actually caused the side effect. Speak to your doctor about your risk for this side effect.

This side effect has also been reported for the other semaglutide products Wegovy and Rybelsus, as well as tirzepatide, the GLP-1/GIP agent approved for type 2 diabetes treatment (Mounjaro) or weight loss (Zepbound).

Why am I using Ozempic?

Ozempic (semaglutide) is medication used alongside diet and exercise to improve blood sugar control in adults with type 2 diabetes. Ozempic is not used to treat type 1 diabetes or diabetic ketoacidosis. You doctor may prescribe Ozempic to be used in addition to other diabetes medications, such as metformin or insulin.

Ozempic is also approved to reduce the risk of major cardiovascular (heart and blood vessel) events such as heart attack, stroke, or death in adults with type 2 diabetes and known heart disease.

How does Ozempic help me?

- Ozempic is in a class of drugs known as glucagon-like peptide-1 (GLP-1) agonists (incretin mimetics).
- Ozempic works by binding to GLP-1 receptors and stimulates insulin release from the pancreas when you need it. It helps to lower your blood sugar levels and A1C.
- It also helps to reduce the amount of sugar released by your liver and slows down food leaving your stomach to help prevent blood sugar spikes. It can reduce your appetite and you may lose weight, as well, although Ozempic is not approved for weight loss.
- Ozempic can help to protect you from a heart attack or stroke if you have type 2 diabetes and known heart disease.
- Ozempic is also approved to reduce the risk of worsening kidney disease and cardiovascular (heart-related) death in patients with type 2 diabetes and chronic kidney disease.

How does Ozempic affect my blood sugar?

In clinical studies conducted by the manufacturer, Ozempic was studied as a single treatment compared to placebo (an inactive agent) as well as when combined with other type 2 diabetes medications such as metformin, metformin plus a sulfonylureas, and metformin plus thiazolidinediones.

The effectiveness of Ozempic was compared to sitagliptin, exenatide extended-release, and insulin glargine. Ozempic 0.5 mg and 1 mg injected weekly significantly reduced the A1C levels in all studies ranging from 30 weeks to 56 weeks.

However, reducing your A1C below 7 may take at least 8 weeks, depending upon where your hemoglobin A1C (HbA1C) is when you start Ozempic. In a 56-week study comparing semaglutide to sitagliptin, Ozempic lowered the mean baseline A1C of 8% down to 7% by week 8 of the study. A1C levels were at or below 6.5% by week 16.

In another clinical study, Ozempic monotherapy lowered the A1C by 1.4% to 1.6% after 30 weeks of treatment. It also reduced fasting blood sugar levels by 41 to 44 mg/dL after 30 weeks. The percent of patients achieving an A1C of less than 7% was 70% to 73% of patients using Ozempic compared to 28% of patients using a placebo.

Bottom Line

Your blood sugar levels should start to fully decline within the first week after you start using Ozempic (semaglutide) at your regular maintenance dose. However, the full effects can take 8 weeks or longer, as this is a long-acting medication that is injected only once per week.

You will start with lower doses for the first 4 weeks to help lower side effects, but this is not an effective dose to lower blood sugar over the long-term.

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