

(Pronounced mown-JAHR-OH)

What Is Mounjaro?

Mounjaro is an injectable prescription medicine that is used along with diet and exercise to improve blood sugar (glucose) in adults with type 2 diabetes mellitus.

Limitations of Use

- It is not known if Mounjaro can be used in people who have had pancreatitis.
- Mounjaro is not for use in people with type 1 diabetes.
- It is not known if Mounjaro is safe and effective for use in children under 18 years of age.

How Mounjaro Works

Mounjaro represents a different class of medicines introduced for adults with type 2 diabetes. It works **differently** by directly activating **GIP** and **GLP-1** pathways to help regulate blood sugar.

GIP: glucose-dependent insulinotropic polypeptide
GLP-1: glucagon-like peptide-1

GIP and GLP-1 are natural incretin hormones responsible for regulating blood sugar levels in response to eating food. GIP is responsible for the majority of this activity which is known as the **incretin effect** in people without type 2 diabetes.¹

The **incretin effect** enhances the release of insulin after a meal and helps lower blood sugar.¹

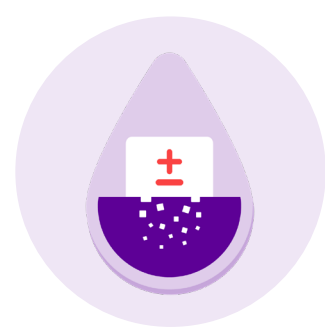
Select Safety Information

Warning

Tell your healthcare provider if you get a lump or swelling in your neck, hoarseness, trouble swallowing, or shortness of breath. These may be symptoms of thyroid cancer. In studies with rats, Mounjaro and medicines that work like Mounjaro caused thyroid tumors, including thyroid cancer. It is not known if Mounjaro will cause thyroid tumors, or a type of thyroid cancer called medullary thyroid carcinoma (MTC) in people. Do not take Mounjaro if you or any of your family have ever had MTC or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

MOUNJARO WORKS IN MULTIPLE WAYS.

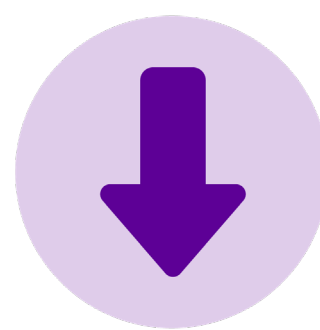
IT HELPS:



The body release insulin when blood sugar is high



The body remove excess sugar from the blood



Stop the liver from making and releasing too much sugar



Reduce how much food is eaten*

*Mounjaro is not a weight loss drug



Slow down how quickly food leaves the stomach, which lessens over time

Select Safety Information

Do not use Mounjaro if you or any of your family have ever had a type of thyroid cancer called MTC or if you have an endocrine system condition called MEN 2, or if you have had a serious allergic reaction to tirzepatide or any of the ingredients in Mounjaro.

How Can Mounjaro Help Adults with Type 2 Diabetes

3 OUT OF 4 PEOPLE TAKING MOUNJARO REACHED an A1C under **7%[†]**

[†] In studies with or without other diabetes medications, 75% to 90% of patients taking Mounjaro reached an A1C of less than 7%, with an average starting A1C of 7.9% to 8.6% across the 5-mg, 10-mg, and 15-mg doses.

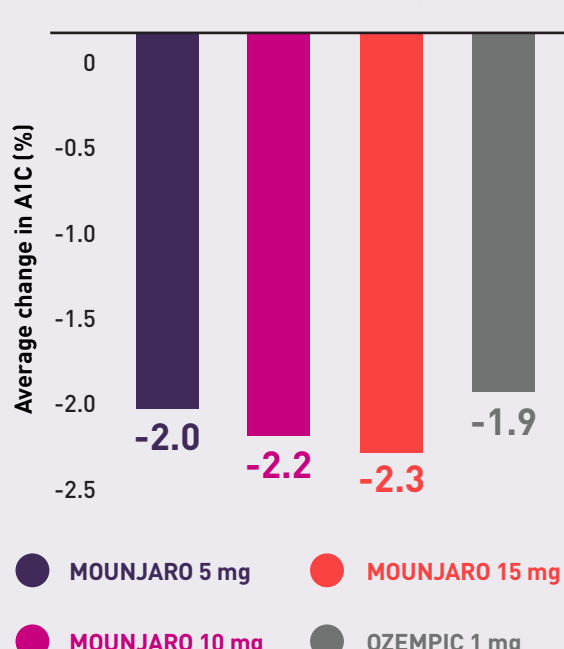
PEOPLE TAKING MOUNJARO lost up to **25 lbs[‡]**

Mounjaro is not a weight loss drug.
[‡] Individual results may vary. In studies with or without other diabetes medications, weight loss in adults ranged from 12 lb (5 mg) to 25 lb (15 mg).

How Mounjaro Performed in Studies with Adults with Type 2 Diabetes

MOUNJARO vs OZEMPIC®

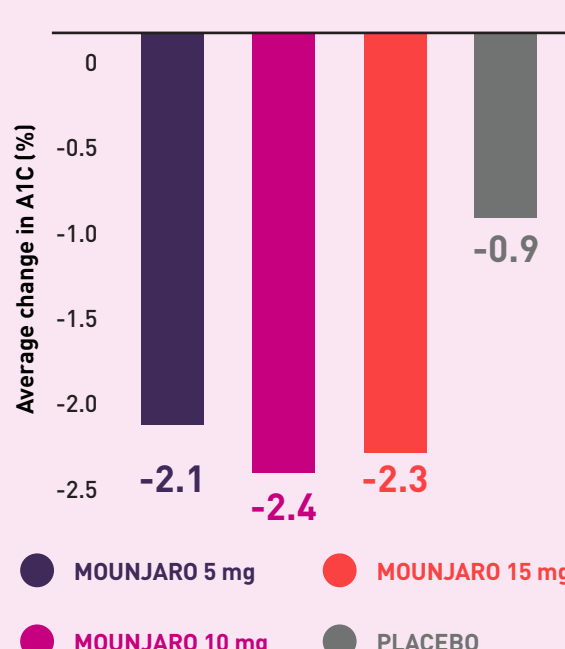
Mounjaro added to metformin lowered A1C more than Ozempic 1 mg[§]



§ In a 40-week study, the Mounjaro 5-mg, 10-mg, and 15-mg doses were compared to Ozempic 1 mg in 1879 adults with type 2 diabetes who were also taking metformin and had a starting A1C of 8.3%.

MOUNJARO vs PLACEBO

Mounjaro added to insulin glargine lowered A1C more than placebo and insulin glargine[¶]



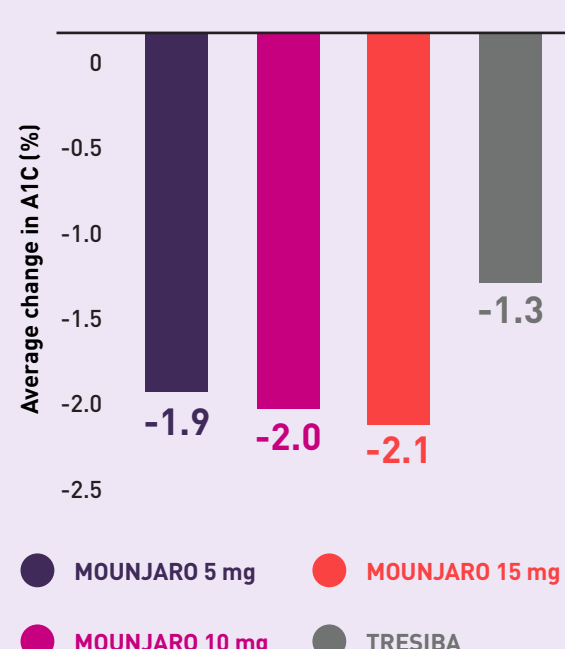
¶ In a 40-week study, the Mounjaro 5-mg, 10-mg, and 15-mg doses were compared to placebo in 475 adults with type 2 diabetes who were also taking insulin glargine. Some study participants were also taking metformin. They had a starting A1C of 8.2% to 8.4%.

SELECT SAFETY INFORMATION

Low blood sugar (hypoglycemia). Your risk for getting low blood sugar may be higher if you use Mounjaro with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin. **Signs and symptoms of low blood sugar may include** dizziness or light-headedness, sweating, confusion or drowsiness, headache, blurred vision, slurred speech, shakiness, fast heartbeat, anxiety, irritability, or mood changes, hunger, weakness, and feeling jittery.

MOUNJARO vs TRESIBA®

Mounjaro added to metformin with or without an SGLT2 inhibitor lowered A1C more than Tresiba^{**}



** In a 52-week study, the Mounjaro 5-mg, 10-mg, and 15-mg doses were compared to titrated Tresiba, a basal insulin, in 1444 adults with type 2 diabetes who were also taking metformin with or without an SGLT2-inhibitor. They had an average starting A1C of 8.1 to 8.2%. At the end of the study, 26% of people on Tresiba met the blood sugar goal (or target). The average daily dose of Tresiba was 49 units per day by the end of the study.

FOR MORE INFORMATION visit mounjaro.com

INDICATION AND SAFETY SUMMARY WITH WARNINGS

Mounjaro® (mown-JAHR-OH) is an injectable medicine for adults with type 2 diabetes used along with diet and exercise to improve blood sugar (glucose).

- It is not known if Mounjaro can be used in people who have had inflammation of the pancreas (pancreatitis). Mounjaro is not for use in people with type 1 diabetes. It is not known if Mounjaro is safe and effective for use in children under 18 years of age.

Warnings

Mounjaro may cause tumors in the thyroid, including thyroid cancer. Watch for possible symptoms, such as a lump or swelling in the neck, hoarseness, trouble swallowing, or shortness of breath. If you have any of these symptoms, tell your healthcare provider.

- Do not use Mounjaro if you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC).
- Do not use Mounjaro if you have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- Do not use Mounjaro if you are allergic to it or any of the ingredients in Mounjaro.

Mounjaro may cause serious side effects, including:

Inflammation of the pancreas (pancreatitis). Stop using Mounjaro and call your healthcare provider right away if you have severe pain in your stomach area (abdomen) that will not go away, with or without vomiting. You may feel the pain from your abdomen to your back.

Low blood sugar (hypoglycemia). Your risk for getting low blood sugar may be higher if you use Mounjaro with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin. **Signs and symptoms of low blood sugar may include** dizziness or light-headedness, sweating, confusion or drowsiness, headache, blurred vision, slurred speech, shakiness, fast heartbeat, anxiety, irritability, or mood changes, hunger, weakness and feeling jittery.

Serious allergic reactions. Stop using Mounjaro and get medical help right away if you have any symptoms of a serious allergic reaction, including swelling of your face, lips, tongue or throat, problems breathing or swallowing, severe rash or itching, fainting or feeling dizzy, and very rapid heartbeat.

Kidney problems (kidney failure). In people who have kidney problems, diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration), which may cause kidney problems to get worse. It is important for you to drink fluids to help reduce your chance of dehydration.

Severe stomach problems. Stomach problems, sometimes severe, have been reported in people who use Mounjaro. Tell your healthcare provider if you have stomach problems that are severe or will not go away.

Changes in vision. Tell your healthcare provider if you have changes in vision during treatment with Mounjaro.

Gallbladder problems. Gallbladder problems have happened in some people who use Mounjaro. Tell your healthcare provider right away if you get symptoms of gallbladder problems, which may include pain in your upper stomach (abdomen), fever, yellowing of skin or eyes (jaundice), and clay-colored stools.

Common Side Effects

The most common side effects of Mounjaro include nausea, diarrhea, decreased appetite, vomiting, constipation, indigestion, and stomach (abdominal) pain. These are not all the possible side effects of Mounjaro. Talk to your healthcare provider about any side effect that bothers you or doesn't go away.

Tell your healthcare provider if you have any side effects. You can report side effects at 1-800-FDA-1088 or www.fda.gov/medwatch.

Before Using Mounjaro

- Your healthcare provider should show you how to use Mounjaro before you use it for the first time.
- Talk to your healthcare provider about low blood sugar and how to manage it.
- If you take birth control pills by mouth, talk to your healthcare provider before you use Mounjaro. Birth control pills may not work as well while using Mounjaro. Your healthcare provider may recommend another type of birth control for 4 weeks after you start Mounjaro and for 4 weeks after each increase in your dose of Mounjaro.

Review these questions with your healthcare provider:

- Do you have other medical conditions, including problems with your pancreas or kidneys, or severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems digesting food?
- Do you take other diabetes medicines, such as insulin or sulfonylureas?
- Do you have a history of diabetic retinopathy?
- Are you pregnant, plan to become pregnant, breastfeeding, or planning to breastfeed? It is not known if Mounjaro will harm your unborn baby or pass into your breast milk.
- Do you take any other prescription medicines or over-the-counter drugs, vitamins, or herbal supplements?

How to Take

- Read the **Instructions for Use** that come with Mounjaro.
- Use Mounjaro exactly as your healthcare provider says.
- Mounjaro is injected under the skin (subcutaneously) of your stomach (abdomen), thigh, or upper arm.
- Use Mounjaro 1 time each week, at any time of the day.
- Do not mix insulin and Mounjaro together in the same injection.
- You may give an injection of Mounjaro and insulin in the same body area (such as your stomach area), but not right next to each other.
- Change (rotate) your injection site with each weekly injection. Do not use the same site for each injection.
- If you take too much Mounjaro, call your healthcare provider or seek medical advice promptly.

LEARN MORE

Mounjaro is a prescription medicine. For more information, call 1-833-807-MJRO (833-807-6576) or go to www.mounjaro.com.

This summary provides basic information about Mounjaro. This does not include all information known about this medicine. Read the information that comes with your prescription each time your prescription is filled. This information does not take the place of talking with your healthcare provider. Be sure to talk to your healthcare provider about Mounjaro and how to take it. Your healthcare provider is the best person to help you decide if Mounjaro is right for you.

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1. Samms RJ, Coghlan MP, Sloop KW. How may GIP enhance the therapeutic efficacy of GLP-1? *Trends Endocrinol Metab.* 2020;31(6):410-421

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